Summary of safety and clinical performance – Medigma's Dental Implants and Abutments – Class IIb

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device Identification and General Information

Device trade name(s): Dental Implants and abutments – See product list in appendix A

Manufacturer's name and address: Medigma Biomedical GmbH, Siemensstraße 10, D-78564 Wehingen, Germany.

Manufacturer's single registration number (SRN): DE-MF-000009412
Basic UDI-DI: See product list in appendix A

Medical device nomenclature description/text: See product GMDN in appendix A

Class of device: IIb

Year when the first certificate (CE) was issued covering the device: Since 2017

Notified Body: MDC Medical Device Certification GmbH., Kriegerstraße 6, D-70191 Stuttgart, Germany, Single identification number: 0483.

2. Intended use of the device

2.1. Intended Purpose

Medigma's dental implants and abutments are intended to be used in conjunction with each other during implant surgical placement in the maxillary and/or mandibular arches to support single-unit or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

2.2. Indications and Target Populations

Medigma's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single-unit or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients.

Dental implants and prosthetics may only be used by dentists or physicians who have had appropriate education and training.

Medigma's dental implants are indicated for:

- Replacing missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla.
- Single-stage or two-stage procedures.
- Immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations.
- When a one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved and the functional load is appropriate.

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Narrow implants identified as Fix Konisch™ ND (3.0mmD) and Fix-1™ One-piece dental implant in diameter of 3.0mm are indicated for use only in replacement of maxillary lateral incisors and mandibular lateral and central incisors.

Medigma's dental abutments are intended for use in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation, to support single and multiple tooth prosthesis in the mandible or maxilla. The prosthesis can be cement-retained, screw-retained to the abutment or overdentures.

Temporary abutments are intended for temporary cement-retained restoration of single crowns and bridges in the anterior and/or posterior regions for use up to six months.
Medigma's healing abutments and cover screws are intended to be used in conjunction with an endosseous dental implant fixture to aid in a healing phase prior to prosthetic rehabilitation in a partially or completely edentulous patient.

2.3. Contraindications and Limitations

- General contraindications associated with elective surgery should be observed.
- It is contraindicated placing abutments in the following cases in patients that are medically unfit for oral surgical procedures and in cases in which safe support of functional loads cannot be achieved.
- Do not use in cases of Allergy or hypersensitivity to one or more of the metals contained in the alloy.
- Special attention, and a thorough evaluation of potential risks and benefits should be given to patients who exhibit underlying medical factors that might affect bone or soft tissue healing processes, for example:
    - Possible contraindications: chronic bleeding problems, psychological impairment, metabolic bone or connective tissue diseases, treatment with corticosteroids, certain cardiac and vascular diseases, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor patient oral hygiene, bruxing, alcoholism.
    - Temporary contraindications: systemic infection, local oral or respiratory infection.
    - Anatomical or pathological contraindications: insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone, both buccally and lingually to the most superior aspect of the implant body; inadequate bone height where proper implant placement would encroach on the mandibular canal; malignancies.
- Special accommodation should be practiced in patients with relative contraindications.
- The placement of dental implants is not recommended in children and under-aged patients, until growth has stopped and epiphyseal closure is completed.
- Local infections or pathologies, inadequate bone volume and/or quality as well as general diseases and treatments affecting bone and soft tissue healing may result in osseointegration failure, both immediately after surgery or at a later stage.
- Narrow platform implants (ND) are contraindicated for use at molar, premolar, and canine restorations.
- It is contraindicated to use UCLA Engaging Conical Connection ND 3.0 in other positions than for lateral incisors in the maxilla or central and/or lateral incisors in the mandible.
- UCLA Engaging Conical Connection ND 3.0 should not be used for multiple unit restorations.
- For Scan Bodies of each platform can only be combined with the corresponding compatible platform. No inappropriate in connection geometry should be used. Scan Bodies may not be modified or changed in any way since it's shape, is essential to ensure an accurate scan result.
- For Ti Pre Milled MDTK Abutment Blank, only compatible connection geometry between Implants and abutments should be used. Any post-processing of the connection geometry to the implant may result in fitting inaccuracies prohibiting further use.

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3. Device Description

3.1. Device Description

Medigma's products are dental implant systems consisting of endosseous dental implants and abutments made of biocompatible materials in various lengths and diameters. All implants (packaged with respective cover screws) are provided sterile using Gamma irradiation in SAL of at least 10^{-6}. The abutments (packaged with respective screws) are provided non-sterile and should be cleaned and steam-sterilized by the clinician before use at the clinic. All Medigma's implants, abutments and respective screws are intended for single-use only.

The dental implant systems are following described:

Implants:

Medigma's dental implant systems consist of endosseous dental implants and compatible abutments are made of Ti 6Al-4V ELI alloy that complies with ASTM F136-13(2021) e1, a biocompatible material, in various lengths and diameters.

The dental implants are surgically inserted into the upper and/or lower jawbone and serve as a substitute or replacement tooth root providing a stable foundation for restorations.

Medigma's implants are available in **AB/AE** (Alumina Oxide Blasted/Acid Etched) or Calcium Phosphate blast surface treatment.

The implants feature one of the following implant platforms:

- Standard internal hex connection – identical platform in all implant diameters.
- Conical hex connection – unique for each implant diameter (featured in Fix Konisch™ dental implants).
- Conical star connection – identical platform in all implant diameters (featured in Grand Konisch™ implants).

Medigma's implant families are as follows:

- **Mars™** – Tapered implants with spiral tap which condenses the bone for immediate stability. The implants have two large variable threads and a tapered core for accurate implant placement. The implants have built-in platform switching. The prosthetic connection in these implants is a standard internal hex connection (IH) regardless of implant diameter. Mars™ implants are featured in AB/AE surface treatment.

- **FixTite™** – Has similar design to Mars™ implants. Has a triple-lead thread design that allows self-drilling, self-cutting and a very fast implant insertion. The prosthetic connection in FixTite™ implants is a standard internal hex connection (IH) and the implants are featured in AB/AE surface treatment.

- **Fix-a-Dent™** – Straight parallel-walled, slightly tapered implant with a V-shaped thread design. It has a double lead thread, a standard internal hex connection and is feature in AB/AE surface treatment.

- **Fix Konisch™** – Tapered-core implants with a spiral tap that promotes increased immediate stability. The implants have double lead thread design (2x1.2mm – for ND, SD and WD platforms). Prosthetic connection in these implants is a conical hex, unique for each diameter (ND – 3.0mmD, SD – 3.5mmD and WD – 4.3/5.0mmD). The implants are featured in Calcium Phosphate blast surface treatment.

- **Grand Konisch™** – Tapered-core implants with a spiral tap that promotes increased immediate stability same as Fix Konisch™. The implants have double lead thread design and a unified internal connection for several Grand Konisch™ implants diameters and lengths. The external shape design is based on Fix Konisch™ SD/WD implants and the usability is similar to Fix Konisch™ system. This system was developed in order to simplifying surgical and prosthetic procedures (reduction in number of platform connections, prosthetic components, tools and accessories).

- **Fix-1™** – A tapered-core spiral implant with integrated abutment post for minimally invasive surgery and immediate loading. The implants have a double lead thread design and are featured in AB/AE surface treatment.

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All implants are packaged together with their respective cover screws, are provided sterile using Gamma irradiation, in the VDmax 20kGy method with accordance to EN ISO 11137-2:2015 in conjunction with ISO/TS 13004:2013, and are intended for single-use.

Abutments:

Medigma's abutments are placed into the dental implant and retained with a screw (the restoration is screw-retained on the implant level) to provide support for a prosthetic restoration. Prosthesis can be cement-retained, screw-retained to the abutment, or overdentures.

Medigma's healing abutments are intended to be used with a dental implant to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing abutments are made of Ti-6Al-4V ELI alloy, provided non-sterile with instructions to be cleaned and steam-sterilized prior to clinical use and are intended for single use only.

Medigma's abutments are made of the following raw materials:

Component Name	Component Material
Healing Abutments, Cement Retained Abutments, Screw Retained Abutments, UCLA Abutments (Bases), Ti Bases, TMA Cementing Cone, Ti Blanks, Ball Attachment, Grip Abutment, Abutment Screw, Implant Cover screw, Metal Housing (accessory)	Titanium alloy Ti 6Al-4V ELI
GoldFix™ Abutment	Gold alloy: 60% Au, 19% Pt, 20% Pd, 1% Ir
CoCrFix™ Abutment	Cobalt-Chrome alloy, compliant with ISO 5832-12:2019 and ASTM F1537-20: Cobalt – max 60%, Chromium – 26-30%, Molybdenum – 5-7%
Sleeves (UCLA Abutment accessories - GoldFix™ Abutment, TitanFix™ Abutment, CoCrFix™ Abutment)	Plastic (burnout plastic casting sleeve): POM-C (Polyoxymethylene)
Ball cap (accessory), Grip Retention males (accessory)	Nylon (Polyamide 12)

All abutments are packaged together with their respective screws (if applicable) and are intended for single-use only. The abutments are provided non-sterile and are intended to be cleaned and steam-sterilized by the clinician prior to use according to the instructions given in the IFU accompanying the device.

Medigma's abutments are divided into several groups per supported prosthetic restoration type:

- **Cement-retained abutments** – the abutment is retained with an abutment screw inside the implant, the prosthesis is cement-retained to the abutment. The abutments are straight or angulated (15°, 25° and 35° for IH platform and Grand Konisch platforms, 15° and 25° for ND platform, 15° for SD and WD platforms)
- **Screw-retained abutments** – the prosthesis is screwed to the abutment with a prosthetic screw. The abutments are straight or angulated (17°, 30° and 45° for IH and Grand Konisch platforms, 17° and 30° for ND, SD and WD platforms).
- **Screw-retained or cement-retained abutments (UCLA abutments)** – are used for customized prosthetic restorations prepared by a dental technician in the laboratory utilizing a cast-on technique. The UCLA abutments consist of a metal base (made of either titanium, gold or cobalt-chrome alloy) compatible with implants' platform connection, a fully burn-out plastic sleeve and a titanium alloy abutment screw used to retain the restoration to the implant.
- **Prosthetic components for CAD/CAM restorations** – enable dentists and dental technicians to design and manufacture individual restorations supported by Medigma's implants.

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- **Ti Bases** allow restoration using superstructures and crowns manufactured from Zirconia and/or other dental metals while utilizing CAD/CAM technology to fit the components provided by Medigma.
- **TMA Cementing Cone** is used as Ti Bases for multi-unit abutments for cementing/gluing CAD/CAM manufactured individual ceramic or metal restorations.
- **Ti Blanks** (Ti Pre-Milled MDTK Abutment Blanks) are used as a raw material for CAM fabrication of a single part (monolithic) individual titanium abutment. The design of the individual abutment is done digitally with CAD software.

- **Overdenture attachments** are used in conjunction with an endosseous dental implant fixture to retain overdentures during the prosthetic rehabilitation process.
  - **Ball Attachments** - used in attachment-retained, tissue-supported multi-unit restorations where the patient is fully edentulous in the arch to be restored. The mechanism consists of a ball abutment secured to the implant by the integrated screw portion. A metal housing and ball cap mechanically retained within the housing, are fixed within the patient's denture.

Screws:

single use screws made of titanium alloy Ti-6Al-4V ELI complying with ASTM F136-13 and ISO 5832-3:2021 and are intended to be used as follows:

- Medigma's implant cover screws are intended to be used with the implant to protect the inner configuration of the implant during the healing process for a short-time use.
- Medigma's abutment screws are intended to secure the abutment to the implant and supplied non-sterile, to be cleaned and steam-sterilized by the clinician prior to use according to the instructions given in the IFU.

3.2. Previous generations

Medigma was CE certified in 2017 offering the market several implant systems with industry traditional Alumina Oxide Blasted/Acid Etched surface treatment (AB/AE) - Mars™, FixTite™, Fix-a-Dent™ and Fix-1™.
In 2020 the line of products was extended by adding the Fix Konisch™ Platform, which were implants with Calcium Phosphate blast surface treatment (different surface treatment from what Medigma was offering until then).
In 2021 another platform was added, the Grand Konisch™ Platform in order to answer the need to simplify surgical and prosthetic procedures (reduction in number of platform connections).
the Grand Konisch™ implants have the same surface treatment as the Fix Konisch™ Platform implants.

Prosthetic Components for CAD/CAM Restorations (Ti-bases, TMA Cementing Cone, Ti Blanks) were a development in 2017 to with components allowing restoration using superstructures and crowns while utilizing CAD/CAM technology (superstructure / crown is designed, using CAD/CAM, to fit the components provided by Medigma). Their range was further increase with additional sizes to supplant clinical needs.

The abutments development was made in parallel to the developments of the implant with the respected connection types (Cement-retained abutments, screw retained abutments, UCLA, TMA, Healing Caps, Overdenture ball attachments).

No significant changes were made to devices design ever since it was firstly introduced to the market, representing products first generation.

3.3. Description of any accessories which are intended to be used in combination with the device

Medigma's device does not fall under the definition of "accessory for a medical device" under the EU MDR article 2(2).

3.4. Description of any other devices and products which are intended to be used in combination with the device

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Medigma Dental implants and abutments are used in conjunction with each other. Medigma's implant cover screws are intended to be used with the implant to protect the inner configuration of the implant during the healing process for a short-time use and Medigma's abutment screws are intended to secure the abutment to the implant. Implants and abutments are used in conjunction with their respected screws. For implantation procedure, adapted drills are used and tools are necessary for connection of abutments to implants.

4. Risks and warnings

4.1. Residual risks and Undesirable Effects

Risk management process for dental implants and abutments was conducted with accordance to EN ISO 14971: 2019-A11:2021 and is part of the technical documentation.

Through the benefit-risk analysis and after mitigating all risks, it was concluded that no additional risks were induced. These residual risks are summarized below:

Risk (Effect of Failure)	Degree of Probability	Mode of Failure	Cause of Failure	Risk Mitigation Activity
Bone tissue contamination/ inflammation, harm to the patient	Between 1:1,000,000 to 1:100,000, Very Low probability, Remote occurrence.	Implant failure	Use of non-sterile product (implant and/ or abutment and/ or tool)	1. IFU warning no to use the implant if the package is damaged. 2. Sterilization instructions in IFU (for abutments, tools, drills, surgical/prosthetic tool kit). 3. Labelling and instructions for single use only of abutments, implants. 4. On-going training and seminars.
Implant rejection, bone loss, harm to the patient, implant migration	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Implant failure and/or bone loss	Insufficient bone volume or bone quality	1. On-going training and seminars. 2. Surgical procedure instructions in user manual. 3. Warnings, precautions, contraindications and IFU for dental implants. 4. Warnings, precautions, contraindications and IFU for prosthetic components and tools, surgical/prosthetic tool kit. 5. Wide range of implants with different diameters and lengths is available - Medigma catalog.

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Risk (Effect of Failure)	Degree of Probability	Mode of Failure	Cause of Failure	Risk Mitigation Activity
Restoration failure, inability to use implant, implant rejection, bone tissue contamination/ inflammation, harm to the patient	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Superstructure fracture	Inadequate planning of restoration	1. On-going training and seminars - Restoration has to be performed by certified technician. 2. Prosthetic components and tools IFU. 3. Scan bodies, Ti-bases and Multi Unit cementing cone IFU. 4. User manual instructions (intended use of the component). 5. Analytical calculations/numerical simulations that take into consideration safety factor of material strength for chosen material, which is sufficiently higher than material yield limit. 6. Grand Konisch regular platform dynamic loading test - "worst case" fatigue test in accordance with ISO 14801. 7. Implant/abutment (stable and fit) connection design - Tolerance analysis of the components and the assembly.
Potential harm to the patient and risk of tissue, including (but not only) contamination/ inflammation damage to vital anatomic structures such as other teeth or implants, maxillary sinus or nerve damage up to permanent paranesthesia, and/or implant rejection.	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Inaccurate drilling or implant insertion	User error, user incompetence	1. Implantation procedure is performed by certified and licensed dentist. 2. On-going training and seminars. 3. Surgical/prosthetic tool kits IFU. 4. Instruction to use drill stopper and radiographic measurement tools, instructions for keeping minimal distance from natural dentition. 5. Wide range of implants diameters and length is available.
	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Implant failure	Inadequate preparation of the cavity (drilling)	1. On-going training and seminars. 2. Drilling protocol instructions in user manual (including recommendations to use drill stoppers). 3. Kit marking for correct usage – Grand Konisch kits specification. 4. Drills marking (described in Medigma's catalog). 5. Recommendation in user manual to use radiographic measurement tools for proper diagnose of drill depth. 6. Grand Konisch implant system user evaluation - intended use validation.

4.2. Warnings and Precautions

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Warnings

- Medigma's dental implants are intended for use only in the indicated applications.
- Appropriate training required prior to using the implant system and improper technique and/or inadequate training can lead to implant failure and/or loss of supportive bone.
- Dental implants must not be altered in any way.
- The use of electro-surgical instruments or lasers around metallic implants and their abutments is not recommended due to the risk of electric and/or heat conductivity.
- Implant mobility, bone loss, or chronic infection may indicate implant failure.
- If the implant becomes contaminated by the patient's body fluids in any way, the implant cannot be used in any other patient.
- Uncleaned and unsterile devices may pose a biological hazard due to tissue contamination. In order to prevent risks associated with such hazards, dispose used devices in accordance to applicable local laws and regulations or according to institutional protocol.
- Do not reuse Implant, cover screws, temporary abutments and abutments, Reuse may lead to an increased risk for the product failure as functionality cannot be guaranteed and in addition, there is a risk of contamination.
- Proper clinical and radiographic evaluation of the patient should be performed prior to any implant placement.
- Implants should not be placed if there is not sufficient alveolar bone width and height to surround and sustain the implant.
- The label "Rx Only" refers to the following caution text: "Federal (USA) law restricts the sale of this device to, or on the order of, a licensed physician or dentist".
- Medigma dental implants and abutments have not been evaluated for safety, compatibility, heating or migration in MR environment.
- Specific warnings for TitanFix/Plastic, GoldFix/Plastic, CoCrFix/Plastic (UCLA) Abutments:
    - Due to the small size of prosthetic components, special care must be taken to ensure that they are not swallowed or aspirated by the patient.
    - For Laboratory Technician: Do not inhale dust and vapors when machining. Ensure suitable air extraction/ventilation at the workplace and corresponding machinery
    - Interactions: Avoid occlusal and approximal contact between different alloy types. Do not use any solutions to remove investment material after casting. These solutions can attack the gold, titanium or cobalt chrome alloys and can damage the abutment.
- Ti Blanks (Ti Pre Milled MDTK Abutment Blank) has to be inspected prior usage. The packing must be sealed without any visible damage. The following descriptions are not sufficient for the immediate use of the product. Dental skills and prior instructions of how to use the product are required.
- Ti Blanks Design limits:
    - Abutment wall thickness ≤ 0.5mm (screw hole to outer abutment surface).
    - Maximum milled abutment height ≤ 10mm
    - Emergence profile diameter ≤ 13mmD
    - Emergence profile height ≤ 6mm
    - Abutment angulation ≤ 25°
    - Abutment taper angle ≤ 6°

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- Abutment sharp edges should be avoided
- Abutment should be rounded occlusally

Precautions

- Used uncleaned and unsterile devices may pose a biological hazard due to tissue contamination. To prevent risks associated with such hazards, dispose used devices in accordance with applicable local laws and regulations or according to institutional protocol.
- The surgical techniques required to place endosseous dental implants require specialized and complex procedures. Formal training for placement of implants is recommended.
- Important: determine local anatomy and suitability at the available bone for implant placement. Adequate radiographs direct palpation and visual inspection of the implant site are necessary prior to treatment, planning and use of Medigma implants.
- Long implants, placed in the maxilla, are only indicated for multiple restorations in splinted applications that utilize at least two implants. For using Medigma's long implants, special attention needs to be paid to available bone volume and critical structures such as nerves, vessels and sinuses.
- Preoperative Considerations and Precautions:
  - Prior to any surgical procedure, patients must be carefully examined and evaluated to determine their medical, psychological and physical status. Attention should be given to factors that may put the patient at risk or factors that may affect bone or soft tissue healing.
  - Panoramic radiographs, as well as CT scans and other individual radiographs must be obtained to enable a complete evaluation of the dental and periodontal status, as well as for the evaluation of available bone for future implant placement.
  - A comprehensive dental treatment plan, including the locations, number and sizes of planned implants should be formulated based on a comprehensive clinical and radiographic evaluation.
  - Constant communication and collaboration between the dental surgeon, the restorative dentist and the dental laboratory technician are critical to ensure optimal outcomes.
  - Whenever applicable, a wax-up and a surgical guide should be used, to ensure correct positioning of dental implants.
  - Sufficient residual bone volume is necessary in order to achieve high primary and long-term success of dental implants. In cases of inadequate bone volume, bone augmentation procedures should be considered.
  - The number of implants and their diameters, lengths and positions in a specific case must take into account the planned prosthetic type and each individual's specific conditions and habits, such as bruxism or unfavorable jaw relations. Incorrect planning and implant placement may result in compromised esthetic results, undesirable restorative outcome, and increase risk of implant overload or mechanical failure.
- Intraoperative Considerations and Precautions:
  - The surgical placement of dental implants requires a high degree of precision and care.
  - Surgical procedures must always be performed using sterile instruments and tools.
  - All efforts must be made to minimize damage to both the soft and bone tissues during the surgical phase. Trauma, thermal injury and infection may result in implant failure or damage to the surrounding tissue.
  - Any divergence from the established surgical protocols increases the risk of osseointegration failure.
  - Loading and healing timing protocols should be determined based on bone quality and the implant's initial stability.
- Prosthetics Consideration sand Precautions

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- Medigma implant systems support all established dental implant restorative options.
- Successful restorative and esthetic outcomes require proper planning related to the number and position of the implants. Treatment planning should also take into account mechanical stress and occlusal force distribution, to prevent excessive transverse loads (particularly in immediate loading cases).
- Passive fit of the prosthesis over implants and abutments is mandatory.
- The use of abutments or other components not manufactured by Medigma may damage their implants. This, in turn, may lead to undesired prosthetic and/or esthetic results, and even to implant failure and damage to bone and soft tissues.
- Medigma short implants are to be used only with straight abutments.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

Medigma has reviewed adverse events as part of its PMS activities related to Medigma's dental implant systems discussed in this clinical evaluation as well as to equivalent devices currently on the market, in order to evaluate whether any events that might affect the safety and performances have occurred.

Vigilance systems of several public health authorities were searched to identify and analyze reported recalls, adverse events and field safety corrective actions - No reported adverse events or recalls related to Medigma's products were found.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

The tables in Appendix B summarize the equivalence comparison of Medigma's dental implant systems, and the commercially available similar devices identified.

Medigma's subject devices were found comparable with other commercially available devices in terms of:

- Same intended use (replacement of missing teeth to restore chewing function in patients).
- Same patient population (partially or fully edentulous patients),
- Same clinical application (surgical placement in jaw bone, immediate loading upon good primary stability and occlusal load)
- Same Material (surface treated titanium alloy for implants, abutments from titanium, gold and cobalt chrome)
- Dimensions (diameters and lengths variations of the implants are similar).

In light of the above it was concluded by Medigma that the subject devices are equivalent to the similar commercially available products

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not applicable

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5.3. Summary of clinical data from other sources, if applicable

Medigma clinical data were obtained from long term PMCF information and users' feedbacks. Being Medigma's Implants and abutments well-established legacy devices with sufficient clinical data and experience since the products were first CE marked (April 2017), additional Clinical studies were not conducted by Medigma.

As part of PMS activities, Medigma reviews and analyzes all received customer complaints and the revealed no trending issues.

The survival rate of Medigma's implant systems is in line with stated in scientific publications for implants by other manufacturers currently on the market (The number of reports of failed implants per year constitutes 1.28%-1.83%).

Analysis of these complaints shows that the majority concerns implantation failure by biological reasons, e.g., mobility, failure to osseointegrate, fibrointegration, infection, pain, no primary stability, etc.

The clinical performance of Medigma's dental implants and abutments is well-established through gathered post market surveillance (PMS) and post market clinical follow-up (PMCF) activities, and that various clinical aspects of dental implant systems are well covered in published literature.

The literature review conducted to identify publications through a search of the scientific literature pertaining to the performance and safety of Medigma's dental implants and abutments and show favorable clinical outcome using its implants and abutments.

5.4. An Overall Summary of The Clinical Performance and Safety

A comprehensive testing program was developed in order to verify that Medigma's dental implant systems meet their specifications and do not raise any new safety and performance issues in comparison to equivalent devices when being used under normal intended conditions.

Medigma's dental implants systems were assessed based on the following tests, performed according to state-of-the-art standards (EU harmonized standards were used where available) in order to verify and validate the safe clinical use of the devices:

- **Biocompatibility Tests**
  Biocompatibility tests were performed on Medigma's dental implants and abutments to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device.
  Titanium implants and abutments were tested for cytotoxicity using guidelines of EN ISO 10993-5:2009, skin sensitization and irritation using guidelines of EN ISO 10993-10:2013.

  Representatives implants with Calcium and AB/AE surface treatments, respectively, IH Angled Titanium Abutments were tested as representatives of all titanium abutments.

  Additional materials used for production of abutments (gold alloy and cobalt chrome alloy) were also subjected to various biocompatibility tests (cytotoxicity, irritation and systemic toxicity for gold alloy, per EN ISO 10993-5:2009, EN ISO 10993-10:2013 and ISO EN ISO 10993-11:2018 and cytotoxicity and chemical characterization per EN ISO 10993-5:2009 and EN ISO 10993-18:2020. Based on test results it was concluded that all materials are biocompatible when used under recommended intended use.

- **Fatigue Testing**
  Fatigue tests of all dental implant systems assembled with abutments were tested using fatigue test in accordance with EN ISO 14801:2016. Per standard requirements, 'worst-case' implant-abutment assembly was chosen for the test. Implants with smallest diameters and cross-sections at implant embedding level were selected and tested as representatives of each implant family.
  Results of the test showed that all implants are within approved Medigma's specification.

- **Gamma Sterilization Validation**
  Medigma's dental implants are provided sterile using gamma radiation, packaged in sterile-barrier system packaging that went through gamma sterilization validation in accordance with VDmax 20kGy method per EN ISO 11137-2:2015 standard in conjunction with ISO/TS 13004:2013.
  Results showed that Sterile Assurance Level (SAL) of at least 10^{-6} is achieved under routine sterilization process which is revalidated using dose audit performed quarterly per EN ISO 11137-2:2015 requirements.

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- **Package Integrity Validation for the Duration of Shelf Life**
  Medigma has two Implants sterile-barrier packaging configurations (with and without a fixture mount) with identical sterile barrier system – outer tube, color coded cap (represent implant diameter).
  The sterile barrier packaging is labeled and packaged in a single unit labeled cardboard box that serves as the secondary packaging with the IFU and two additional peel-off identification labels as the one affixed to the box.
  Integrity of sterile-barrier packaging employed by Medigma for sterile dental implants was validated in accordance with EN ISO 11607-1:2020.
  The packaging was subjected to several treatments prior to integrity testing: shelf life under real time and accelerated aging conditions, two-gamma radiation cycles and transportation simulation.
  Based on results for performed tests it was concluded that integrity of sterile-barrier packaging as well as sterility of the implants remain through shelf life defined as five years and through transportation processes.
  Medigma's Abutments are provided non-sterile as a stand-alone device packed together with its compatible screw in a single-unit pouch packaging made of PET+BOPP+PE.
  The packaging is intended to keep the device identified and protected from dust and for transportation only.
  Shelf life is defined in the relevant IFU as to grinding aspects due to usage period.
  Transportation validation of Medigma's implant systems devices were validated for integrity in transportation simulation testing in accordance with ASTM D4169-16 and ASTM D4332-14.
  All products configurations meet the acceptance criteria that were defined for the test.

- **Steam-Sterilization Validation for Non-Sterile Devices**
  Medigma's abutments are provided non-sterile, for single use. The end user (clinician) is instructed to clean and steam-sterilize the abutments prior to clinical use. Steam-sterilization method recommended by Medigma was validated in accordance with EN ISO 17665-1:2006. Based on results of this validation study it was concluded that steam-sterilization method recommended by Medigma achieves SAL of at least 10^{-6}.

5.5. Ongoing or planned post-market clinical follow-up

Post Marketing Clinical Follow-up (PMCF) Plan, a decision is made on conducting PMCF study based on data collected through PMS activities, in order to confirm clinical performance and safety of the device. The decision about conducting PMCF will be accepted if the criteria for such study will be met per the PMCF approved plan.

Based on PMS data for 2021 as conducted by Medigma, potential adverse events reviewed through vigilance databases as well as other criteria from the PMCF plan, it was determined that no new risks in regards with device's clinical safety and effectiveness were raised.

6. Possible diagnostic or therapeutic alternatives

Not applicable.

7. Suggested profile and training for users

All the intended users are licensed dentists or lab technicians which are specialized in the dental implant field and as such are having the technical knowledge, experience, education and the necessary training. In addition, Medigma provided intended users with the necessary information (warning, instruction for use, contraindication) through IFU, user manuals and additional training/guidance when deemed necessary.

8. Reference to any harmonized standards and CS applied

See list of applied standards and common specifications in Appendix C.

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9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	02.06.2022	First edition	☐Yes Validation language: ☒ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
1.0a	29.06.2023	Information about product history was added	☐Yes Validation language: ☒ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
			☐ Yes Validation language: ☐ No

Appendices

Appendix A - List of Class IIb Products covered under Medigma Biomedical GmbH

Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
Dental Implants				
Fix-a-Dent™ Dental Implant				
STA-3310	4260525162508	Fix-a-Dent Dental Implant 3.3D 10L	55849	426052516ImplantsDD
STA-3311	4260525162515	Fix-a-Dent™ Dental Implant 3.3D 11.5L	55849	426052516ImplantsDD
STA-3313	4260525162522	Fix-a-Dent™ Dental Implant 3.3D 13L	55849	426052516ImplantsDD
STA-3316	4260525162539	Fix-a-Dent™ Dental Implant 3.3D 16L	55849	426052516ImplantsDD
STA-3318	4260525162546	Fix-a-Dent™ Dental Implant 3.3D 18L	55849	426052516ImplantsDD
STA-3708	4260525162553	Fix-a-Dent™ Dental Implant 3.75D 8L	55849	426052516ImplantsDD
STA-3710	4260525162560	Fix-a-Dent™ Dental Implant 3.75D 10L	55849	426052516ImplantsDD
STA-3711	4260525162577	Fix-a-Dent™ Dental Implant 3.75D 11.5L	55849	426052516ImplantsDD
STA-3713	4260525162584	Fix-a-Dent™ Dental Implant 3.75D 13L	55849	426052516ImplantsDD
STA-3716	4260525162591	Fix-a-Dent™ Dental Implant 3.75D 16L	55849	426052516ImplantsDD
STA-3718	4260525162607	Fix-a-Dent™ Dental Implant 3.75D 18L	55849	426052516ImplantsDD
STA-4206	4260525162614	Fix-a-Dent™ Dental Implant 4.2D 6.25L	55849	426052516ImplantsDD
STA-4208	4260525162621	Fix-a-Dent™ Dental Implant 4.2D 8L	55849	426052516ImplantsDD
STA-4210	4260525162638	Fix-a-Dent™ Dental Implant 4.2D 10L	55849	426052516ImplantsDD
STA-4211	4260525162645	Fix-a-Dent™ Dental Implant 4.2D 11.5L	55849	426052516ImplantsDD
STA-4213	4260525162652	Fix-a-Dent™ Dental Implant 4.2D 13L	55849	426052516ImplantsDD
STA-4216	4260525162669	Fix-a-Dent™ Dental Implant 4.2D 16L	55849	426052516ImplantsDD
STA-4218	4260525162676	Fix-a-Dent™ Dental Implant 4.2D 18L	55849	426052516ImplantsDD
STA-5006	4260525162683	Fix-a-Dent™ Dental Implant 5.0D 6.25L	55849	426052516ImplantsDD
STA-5008	4260525162690	Fix-a-Dent™ Dental Implant 5.0D 8L	55849	426052516ImplantsDD

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
STA-5010	4260525162706	Fix-a-Dent™ Dental Implant 5.0D 10L	55849	426052516ImplantsDD
STA-5011	4260525162713	Fix-a-Dent™ Dental Implant 5.0D 11.5L	55849	426052516ImplantsDD
STA-5013	4260525162720	Fix-a-Dent™ Dental Implant 5.0D 13L	55849	426052516ImplantsDD
STA-5016	4260525162737	Fix-a-Dent™ Dental Implant 5.0D 16L	55849	426052516ImplantsDD
STA-6006	4260525162744	Fix-a-Dent™ Dental Implant 6.0D 6.25L	55849	426052516ImplantsDD
STA-6008	4260525162751	Fix-a-Dent™ Dental Implant 6.0D 8L	55849	426052516ImplantsDD
STA-6010	4260525162768	Fix-a-Dent™ Dental Implant 6.0D 10L	55849	426052516ImplantsDD
STA-6011	4260525162775	Fix-a-Dent™ Dental Implant 6.0D 11.5L	55849	426052516ImplantsDD
STA-6013	4260525162782	Fix-a-Dent™ Dental Implant 6.0D 13L	55849	426052516ImplantsDD
Mars™ Dental Implant				
113508	4260525160306	Mars™ Dental Implant 3.5D 8L	55849	426052516ImplantsDD
113510	4260525160313	Mars™ Dental Implant 3.5D 10L	55849	426052516ImplantsDD
113511	4260525160320	Mars™ Dental Implant 3.5D 11.5L	55849	426052516ImplantsDD
113513	4260525160337	Mars™ Dental Implant 3.5D 13L	55849	426052516ImplantsDD
113516	4260525160344	Mars™ Dental Implant 3.5D 16L	55849	426052516ImplantsDD
113518	4260525160351	Mars™ Dental Implant 3.5D 18L	55849	426052516ImplantsDD
113808	4260525160368	Mars™ Dental Implant 3.75D 8L	55849	426052516ImplantsDD
113810	4260525160375	Mars™ Dental Implant 3.75D 10L	55849	426052516ImplantsDD
113811	4260525160382	Mars™ Dental Implant 3.75D 11.5L	55849	426052516ImplantsDD
113813	4260525160399	Mars™ Dental Implant 3.75D 13L	55849	426052516ImplantsDD
113816	4260525160405	Mars™ Dental Implant 3.75D 16L	55849	426052516ImplantsDD
113818	4260525160412	Mars™ Dental Implant 3.75D 18L	55849	426052516ImplantsDD
114206	4260525160429	Mars™ Dental Implant 4.2D 6.25L	55849	426052516ImplantsDD
114208	4260525160436	Mars™ Dental Implant 4.2D 8L	55849	426052516ImplantsDD
114210	4260525160443	Mars™ Dental Implant 4.2D 10L	55849	426052516ImplantsDD
114211	4260525160450	Mars™ Dental Implant 4.2D 11.5L	55849	426052516ImplantsDD
114213	4260525160467	Mars™ Dental Implant 4.2D 13L	55849	426052516ImplantsDD
114216	4260525160474	Mars™ Dental Implant 4.2D 16L	55849	426052516ImplantsDD
114218	4260525160481	Mars™ Dental Implant 4.2D 18L	55849	426052516ImplantsDD
115006	4260525160498	Mars™ Dental Implant 5.0D 6.25L	55849	426052516ImplantsDD
115008	4260525160504	Mars™ Dental Implant 5.0D 8L	55849	426052516ImplantsDD
115010	4260525160511	Mars™ Dental Implant 5.0D 10L	55849	426052516ImplantsDD
115011	4260525160528	Mars™ Dental Implant 5.0D 11.5L	55849	426052516ImplantsDD
115013	4260525160535	Mars™ Dental Implant 5.0D 13L	55849	426052516ImplantsDD
115016	4260525160542	Mars™ Dental Implant 5.0D 16L	55849	426052516ImplantsDD
116006	4260525160559	Mars™ Dental Implant 6.0D 6.25L	55849	426052516ImplantsDD
116008	4260525160566	Mars™ Dental Implant 6.0D 8L	55849	426052516ImplantsDD
116010	4260525160573	Mars™ Dental Implant 6.0D 10L	55849	426052516ImplantsDD
116011	4260525160580	Mars™ Dental Implant 6.0D 11.5L	55849	426052516ImplantsDD

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116013	4260525160597	Mars™ Dental Implant 6.0D 13L	55849	426052516ImplantsDD
Fix Konisch™ ND Dental Implant				
FKND0830	4260525164335	Fix Konisch™ NP Dental Implant 3.0D 8L	55849	426052516ImplantsDD
FKND1030	4260525164342	Fix Konisch™ Narrow Dental Implant 3.0D 10L	55849	426052516ImplantsDD
FKND1130	4260525164359	Fix Konisch™ Narrow Dental Implant 3.0D 11.5L	55849	426052516ImplantsDD
FKND1330	4260525164366	Fix Konisch™ Narrow Dental Implant 3.0D 13L	55849	426052516ImplantsDD
FKND1630	4260525164373	Fix Konisch™ Narrow Dental Implant 3.0D 16L	55849	426052516ImplantsDD
FKND1830	4260525164380	Fix Konisch™ Narrow Dental Implant 3.0D 18L	55849	426052516ImplantsDD
Fix Konisch™ SD Dental Implant				
FKSW0835	4260525164397	Fix Konisch™ Standard Dental Implant 3.5D 8.0L	55849	426052516ImplantsDD
FKSW1035	4260525164427	Fix Konisch™ Standard Dental Implant 3.5D 10L	55849	426052516ImplantsDD
FKSW1135	4260525164458	Fix Konisch™ Standard Dental Implant 3.5D 11.5L	55849	426052516ImplantsDD
FKSW1335	4260525164489	Fix Konisch™ Standard Dental Implant 3.5D 13L	55849	426052516ImplantsDD
FKSW1535	4260525164519	Fix Konisch™ Standard Dental Implant 3.5D 15L	55849	426052516ImplantsDD
FKSW1835	4260525164540	Fix Konisch™ Standard Dental Implant 3.5D 18L	55849	426052516ImplantsDD
Fix Konisch™ WD Dental Implant				
FKSW0843	4260525164403	Fix Konisch™ Wide Dental Implant 4.3D 8.0L	55849	426052516ImplantsDD
FKSW1043	4260525164434	Fix Konisch™ Wide Dental Implant 4.3D 10L	55849	426052516ImplantsDD
FKSW1143	4260525164465	Fix Konisch™ Wide Dental Implant 4.3D 11.5L	55849	426052516ImplantsDD
FKSW1343	4260525164496	Fix Konisch™ Wide Dental Implant 4.3D 13L	55849	426052516ImplantsDD
FKSW1543	4260525164526	Fix Konisch™ Wide Dental Implant 4.3D 15L	55849	426052516ImplantsDD
FKSW1843	4260525164557	Fix Konisch™ Wide Dental Implant 4.3D 18L	55849	426052516ImplantsDD
FKSW2043	4260525164571	Fix Konisch™ Wide Dental Implant 4.3D 20L	55849	426052516ImplantsDD
FKSW2243	4260525164588	Fix Konisch™ Wide Dental Implant 4.3D 22.5L	55849	426052516ImplantsDD
FKSW2543	4260525164595	Fix Konisch™ Wide Dental Implant 4.3D 25L	55849	426052516ImplantsDD
FKSW0849	4260525164410	Fix Konisch™ Wide Dental Implant 5D 8.0L	55849	426052516ImplantsDD
FKSW1049	4260525164441	Fix Konisch™ Wide Dental Implant 5D 10L	55849	426052516ImplantsDD
FKSW1149	4260525164472	Fix Konisch™ Wide Dental Implant 5D 11.5L	55849	426052516ImplantsDD
FKSW1349	4260525164502	Fix Konisch™ Wide Dental Implant 5D 13L	55849	426052516ImplantsDD
FKSW1549	4260525164533	Fix Konisch™ Wide Dental Implant 5D 15L	55849	426052516ImplantsDD
FKSW1849	4260525164564	Fix Konisch™ Wide Dental Implant 5D 18L	55849	426052516ImplantsDD
Fix-Tite™ Spiral Dental Implant				
35081	4260525169996	FixTite™-S spiral Dental Implant S 3.5D 8L	55849	426052516ImplantsDD
35101	4260525160009	FixTite™-S spiral Dental Implant S 3.5D 10L	55849	426052516ImplantsDD
35111	4260525160016	FixTite™-S spiral Dental Implant S 3.5D 11.5L	55849	426052516ImplantsDD
35131	4260525160023	FixTite™-S spiral Dental Implant S 3.5D 13L	55849	426052516ImplantsDD
35161	4260525160030	FixTite™-S spiral Dental Implant S 3.5D 16L	55849	426052516ImplantsDD
35181	4260525160047	FixTite™-S spiral Dental Implant S 3.5D 18L	55849	426052516ImplantsDD
37081	4260525160054	FixTite™-S spiral Dental Implant S 3.75D 8L	55849	426052516ImplantsDD

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
37101	4260525160061	FixTite™-S spiral Dental Implant S 3.75D 10L	55849	426052516ImplantsDD
37111	4260525160078	FixTite™-S spiral Dental Implant S 3.75D 11.5L	55849	426052516ImplantsDD
37131	4260525160085	FixTite™-S spiral Dental Implant S 3.75D 13L	55849	426052516ImplantsDD
37161	4260525160092	FixTite™-S spiral Dental Implant S 3.75D 16L	55849	426052516ImplantsDD
37181	4260525160108	FixTite™-S spiral Dental Implant S 3.75D 18L	55849	426052516ImplantsDD
42061	4260525160115	FixTite™-S spiral Dental Implant S 4.2D 6.25L	55849	426052516ImplantsDD
42081	4260525160122	FixTite™-S spiral Dental Implant S 4.2D 8L	55849	426052516ImplantsDD
42101	4260525160139	FixTite™-S spiral Dental Implant S 4.2D 10L	55849	426052516ImplantsDD
42111	4260525160146	FixTite™-S spiral Dental Implant S 4.2D 11.5L	55849	426052516ImplantsDD
42131	4260525160153	FixTite™-S spiral Dental Implant S 4.2D 13L	55849	426052516ImplantsDD
42161	4260525160160	FixTite™-S spiral Dental Implant S 4.2D 16L	55849	426052516ImplantsDD
42181	4260525160177	FixTite™-S spiral Dental Implant S 4.2D 18L	55849	426052516ImplantsDD
50061	4260525160184	FixTite™-S spiral Dental Implant S 5.0D 6.25L	55849	426052516ImplantsDD
50081	4260525160191	FixTite™-S spiral Dental Implant S 5.0D 8L	55849	426052516ImplantsDD
50101	4260525160207	FixTite™-S spiral Dental Implant S 5.0D 10L	55849	426052516ImplantsDD
50111	4260525160214	FixTite™-S spiral Dental Implant S 5.0D 11.5L	55849	426052516ImplantsDD
50131	4260525160221	FixTite™-S spiral Dental Implant S 5.0D 13L	55849	426052516ImplantsDD
50161	4260525160238	FixTite™-S spiral Dental Implant S 5.0D 16L	55849	426052516ImplantsDD
60061	4260525160245	FixTite™-S spiral Dental Implant S 6.0D 6.25L	55849	426052516ImplantsDD
60081	4260525160252	FixTite™-S spiral Dental Implant S 6.0D 8L	55849	426052516ImplantsDD
60101	4260525160269	FixTite™-S spiral Dental Implant S 6.0D 10L	55849	426052516ImplantsDD
60111	4260525160276	FixTite™-S spiral Dental Implant S 6.0D 11.5L	55849	426052516ImplantsDD
60131	4260525160283	FixTite™-S spiral Dental Implant S 6.0D 13L	55849	426052516ImplantsDD
60161	4260525160290	FixTite™-S spiral Dental Implant S 6.0D 16L	55849	426052516ImplantsDD
Fix-1™ Dental Implant				
FO-3010	4260525161624	One Piece Implant 3.0D 10L	55848	426052516ImplantsDD
FO-3011	4260525161631	One Piece Implant 3.0D 11.5L	55848	426052516ImplantsDD
FO-3013	4260525161648	One Piece Implant 3.0D 13L	55848	426052516ImplantsDD
FO-3015	4260525161655	One Piece Implant 3.0D 15L	55848	426052516ImplantsDD
FO-3310	4260525161662	One Piece Implant 3.3D 10L	55848	426052516ImplantsDD
FO-3311	4260525161679	One Piece Implant 3.3D 11.5L	55848	426052516ImplantsDD
FO-3313	4260525161686	One Piece Implant 3.3D 13L	55848	426052516ImplantsDD
FO-3315	4260525161693	One Piece Implant 3.3D 15L	55848	426052516ImplantsDD
FO-3610	4260525161709	One Piece Implant 3.6D 10L	55848	426052516ImplantsDD
FO-3611	4260525161716	One Piece Implant 3.6D 11.5L	55848	426052516ImplantsDD
FO-3613	4260525161723	One Piece Implant 3.6D 13L	55848	426052516ImplantsDD
FO-3615	4260525161730	One Piece Implant 3.6D 15L	55848	426052516ImplantsDD
FO-4210	4260525161747	One Piece Implant 4.2D 10L	55848	426052516ImplantsDD
FO-4211	4260525161754	One Piece Implant 4.2D 11.5L	55848	426052516ImplantsDD

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FO-4213	4260525161761	One Piece Implant 4.2D 13L	55848	426052516ImplantsDD
FO-4215	4260525161778	One Piece Implant 4.2D 15L	55848	426052516ImplantsDD
FO-5010	4260525161785	One Piece Implant 5.0D 10L	55848	426052516ImplantsDD
FO-5011	4260525161792	One Piece Implant 5.0D 11.5L	55848	426052516ImplantsDD
FO-5013	4260525161808	One Piece Implant 5.0D 13L	55848	426052516ImplantsDD
FO-5015	4260525161815	One Piece Implant 5.0D 15L	55848	426052516ImplantsDD
Grand Konisch™ Dental Implant				
MGKI0643	4260525169231	Grand Konisch™ Dental Implant 4.3D 6.0L	55849	426052516ImplantsDD
MGKI0650	4260525169248	Grand Konisch™ Dental Implant 5D 6.0L	55849	426052516ImplantsDD
MGKI0660	4260525169255	Grand Konisch™ Dental Implant 6D 6.0L	55849	426052516ImplantsDD
MGKI0835	4260525169262	Grand Konisch™ Dental Implant 3.5D 8.0L	55849	426052516ImplantsDD
MGKI0838	4260525169279	Grand Konisch™ Dental Implant 3.75D 8.0L	55849	426052516ImplantsDD
MGKI0843	4260525169286	Grand Konisch™ Dental Implant 4.3D 8.0L	55849	426052516ImplantsDD
MGKI0850	4260525169293	Grand Konisch™ Dental Implant 5D 8.0L	55849	426052516ImplantsDD
MGKI0860	4260525169309	Grand Konisch™ Dental Implant 6D 8.0L	55849	426052516ImplantsDD
MGKI1035	4260525169316	Grand Konisch™ Dental Implant 3.5D 10L	55849	426052516ImplantsDD
MGKI1038	4260525169323	Grand Konisch™ Dental Implant 3.75D 10L	55849	426052516ImplantsDD
MGKI1043	4260525169330	Grand Konisch™ Dental Implant 4.3D 10L	55849	426052516ImplantsDD
MGKI1050	4260525169347	Grand Konisch™ Dental Implant 5D 10L	55849	426052516ImplantsDD
MGKI1060	4260525169354	Grand Konisch™ Dental Implant 6D 10L	55849	426052516ImplantsDD
MGKI1135	4260525169361	Grand Konisch™ Dental Implant 3.5D 11.5L	55849	426052516ImplantsDD
MGKI1138	4260525169378	Grand Konisch™ Dental Implant 3.75D 11.5L	55849	426052516ImplantsDD
MGKI1143	4260525169385	Grand Konisch™ Dental Implant 4.3D 11.5L	55849	426052516ImplantsDD
MGKI1150	4260525169392	Grand Konisch™ Dental Implant 5D 11.5L	55849	426052516ImplantsDD
MGKI1160	4260525169408	Grand Konisch™ Dental Implant 6D 11.5L	55849	426052516ImplantsDD
MGKI1335	4260525169415	Grand Konisch™ Dental Implant 3.5D 13L	55849	426052516ImplantsDD
MGKI1338	4260525169422	Grand Konisch™ Dental Implant 3.75D 13L	55849	426052516ImplantsDD
MGKI1343	4260525169439	Grand Konisch™ Dental Implant 4.3D 13L	55849	426052516ImplantsDD
MGKI1350	4260525169446	Grand Konisch™ Dental Implant 5D 13L	55849	426052516ImplantsDD
MGKI1360	4260525169453	Grand Konisch™ Dental Implant 6D 13L	55849	426052516ImplantsDD
MGKI1635	4260525169460	Grand Konisch™ Dental Implant 3.5D 16L	55849	426052516ImplantsDD
MGKI1638	4260525169477	Grand Konisch™ Dental Implant 3.75D 16L	55849	426052516ImplantsDD
MGKI1643	4260525169484	Grand Konisch™ Dental Implant 4.3D 16L	55849	426052516ImplantsDD
MGKI1650	4260525169491	Grand Konisch™ Dental Implant 5D 16L	55849	426052516ImplantsDD
MGKI1835	4260525169507	Grand Konisch™ Dental Implant 3.5D 18L	55849	426052516ImplantsDD
MGKI1838	4260525169514	Grand Konisch™ Dental Implant 3.75D 18L	55849	426052516ImplantsDD
MGKI1843	4260525169521	Grand Konisch™ Dental Implant 4.3D 18L	55849	426052516ImplantsDD
MGKI1850	4260525169538	Grand Konisch™ Dental Implant 5D 18L	55849	426052516ImplantsDD
MGKI2038	4260525169545	Grand Konisch™ Dental Implant 3.75D 20L	55849	426052516ImplantsDD

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
MGKI2043	4260525169552	Grand Konisch™ Dental Implant 4.3D 20L	55849	426052516ImplantsDD
MGKI2050	4260525169569	Grand Konisch™ Dental Implant 5D 20L	55849	426052516ImplantsDD
MGKI2238	4260525169576	Grand Konisch™ Dental Implant 3.75D 22.5L	55849	426052516ImplantsDD
MGKI2243	4260525169583	Grand Konisch™ Dental Implant 4.3D 22.5L	55849	426052516ImplantsDD
MGKI2250	4260525169590	Grand Konisch™ Dental Implant 5D 22.5L	55849	426052516ImplantsDD
MGKI2538	4260525169606	Grand Konisch™ Dental Implant 3.75D 25L	55849	426052516ImplantsDD
MGKI2543	4260525169613	Grand Konisch™ Dental Implant 4.3D 25L	55849	426052516ImplantsDD
MGKI2550	4260525169620	Grand Konisch™ Dental Implant 5D 25L	55849	426052516ImplantsDD
Healing Abutments				
IH Healing Abutment				
TGH2-SL	4260525162904	Slim Healing Abutment 3.5mmDX2mmL	44880	426052516AbutmentSup3B
TGH3-SL	4260525162935	Slim Healing Abutment 3.5mmDX3mmL	44880	426052516AbutmentSup3B
TGH4-SL	4260525162959	Slim Healing Abutment 3.5mmDX4mmL	44880	426052516AbutmentSup3B
TGH5-SL	4260525162980	Slim Healing Abutment 3.5mmDX5mmL	44880	426052516AbutmentSup3B
TGH6-SL	4260525163017	Slim Healing Abutment 3.5mmDX6mmL	44880	426052516AbutmentSup3B
TGH2-ST	4260525162911	Healing Abutment 4.5mmD x 2mmL	44880	426052516AbutmentSup3B
TGH3-ST	4260525162942	Healing Abutment 4.5mmD x 3mmL	44880	426052516AbutmentSup3B
TGH4-ST	4260525162966	Healing Abutment 4.5mmD x 4mmL	44880	426052516AbutmentSup3B
TGH5-ST	4260525162997	Healing Abutment 4.5mmD x 5mmL	44880	426052516AbutmentSup3B
TGH6-ST	4260525163024	Healing Abutment 4.5mmD x 6mmL	44880	426052516AbutmentSup3B
TGH2-WD	4260525162928	Wide Healing Abutment 6mmD X 2mmL	44880	426052516AbutmentSup3B
MIH3013	4260525166964	IH Wide Healing Abutment 6mmD x 3mmL	44880	426052516AbutmentSup3B
TGH4-WD	4260525162973	Wide Healing Abutment 6mmD X 4mmL	44880	426052516AbutmentSup3B
TGH5-WD	4260525163000	Wide Healing Abutment 6mmD X 5mmL	44880	426052516AbutmentSup3B
ND Healing Abutment				
MND0046	4260525165042	ND Slim Healing Abutment 3mmD x 2mmL	44880	426052516AbutmentSup3B
MND0047	4260525165059	ND Slim Healing Abutment 3mmD x 3mmL	44880	426052516AbutmentSup3B
MND0048	4260525165066	ND Slim Healing Abutment 3mmD x 4mmL	44880	426052516AbutmentSup3B
MND0049	4260525165073	ND Slim Healing Abutment 3mmD x 5mmL	44880	426052516AbutmentSup3B
MND0050	4260525165080	ND Slim Healing Abutment 3mmD x 6mmL	44880	426052516AbutmentSup3B
MND0004	4260525164632	ND Healing Abutment 4.5mmD x 2mmL	44880	426052516AbutmentSup3B
MND0008	4260525164670	ND Healing Abutment 4.5mmD x 3mmL	44880	426052516AbutmentSup3B
MND0009	4260525164687	ND Healing Abutment 4.5mmD x 4mmL	44880	426052516AbutmentSup3B
MND0012	4260525164717	ND Healing Abutment 4.5mmD x 5mmL	44880	426052516AbutmentSup3B
MND0013	4260525164724	ND Healing Abutment 4.5mmD x 6mmL	44880	426052516AbutmentSup3B
MND0090	4260525165325	ND Conical Healing Abutment 4.5mmD x 2mmL	44880	426052516AbutmentSup3B
MND0091	4260525165332	ND Conical Healing Abutment 4.5mmD x 3mmL	44880	426052516AbutmentSup3B
MND0092	4260525165349	ND Conical Healing Abutment 4.5mmD x 4mmL	44880	426052516AbutmentSup3B
MND0093	4260525165356	ND Conical Healing Abutment 4.5mmD x 5mmL	44880	426052516AbutmentSup3B

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
MND0094	4260525165363	ND Conical Healing Abutment 4.5mmD x 6mmL	44880	426052516AbutmentSup3B
SD Healing Abutment				
MSD0046	4260525166049	SD Slim Healing Abutment 3.5mmD x 2mmL	44880	426052516AbutmentSup3B
MSD0047	4260525166056	SD Slim Healing Abutment 3.5mmD x 3mmL	44880	426052516AbutmentSup3B
MSD0048	4260525166063	SD Slim Healing Abutment 3.5mmD x 4mmL	44880	426052516AbutmentSup3B
MSD0049	4260525166070	SD Slim Healing Abutment 3.5mmD x 5mmL	44880	426052516AbutmentSup3B
MSD0050	4260525166087	SD Slim Healing Abutment 3.5mmD x 6mmL	44880	426052516AbutmentSup3B
MSD0022	4260525169088	SD Healing Abutment 4.5mmD x 2mmL	44880	426052516AbutmentSup3B
MSD0023	4260525169095	SD Healing Abutment 4.5mmD x 3mmL	44880	426052516AbutmentSup3B
MSD0024	4260525169101	SD Healing Abutment 4.5mmD x 4mmL	44880	426052516AbutmentSup3B
MSD0025	4260525169118	SD Healing Abutment 4.5mmD x 5mmL	44880	426052516AbutmentSup3B
MSD0026	4260525169125	SD Healing Abutment 4.5mmD x 6mmL	44880	426052516AbutmentSup3B
MSD0090	4260525166384	SD Conical Healing Abutment 4.5mmD x 2mmL	44880	426052516AbutmentSup3B
MSD0091	4260525166391	SD Conical Healing Abutment 4.5mmD x 3mmL	44880	426052516AbutmentSup3B
MSD0092	4260525166407	SD Conical Healing Abutment 4.5mmD x 4mmL	44880	426052516AbutmentSup3B
MSD0093	4260525166414	SD Conical Healing Abutment 4.5mmD x 5mmL	44880	426052516AbutmentSup3B
MSD0094	4260525166421	SD Conical Healing Abutment 4.5mmD x 6mmL	44880	426052516AbutmentSup3B
WD Healing Abutment				
MWD0046	4260525168265	WD Slim Healing Abutment 4mmD x 2mmL	44880	426052516AbutmentSup3B
MWD0047	4260525168272	WD Slim Healing Abutment 4mmD x 3mmL	44880	426052516AbutmentSup3B
MWD0048	4260525168289	WD Slim Healing Abutment 4mmD x 4mmL	44880	426052516AbutmentSup3B
MWD0049	4260525168296	WD Slim Healing Abutment 4mmD x 5mmL	44880	426052516AbutmentSup3B
MWD0050	4260525168302	WD Slim Healing Abutment 4mmD x 6mmL	44880	426052516AbutmentSup3B
MWD0022	4260525168142	WD Healing Abutment 5.5mmD x 2mmL	44880	426052516AbutmentSup3B
MWD0023	4260525168159	WD Healing Abutment 5.5mmD x 3mmL	44880	426052516AbutmentSup3B
MWD0024	4260525168166	WD Healing Abutment 5.5mmD x 4mmL	44880	426052516AbutmentSup3B
MWD0025	4260525168173	WD Healing Abutment 5.5mmD x 5mmL	44880	426052516AbutmentSup3B
MWD0026	4260525168180	WD Healing Abutment 5.5mmD x 6mmL	44880	426052516AbutmentSup3B
MWD0090	4260525168586	WD Conical Healing Abutment 5.5mmD x 2mmL	44880	426052516AbutmentSup3B
MWD0091	4260525168593	WD Conical Healing Abutment 5.5mmD x 3mmL	44880	426052516AbutmentSup3B
MWD0092	4260525168609	WD Conical Healing Abutment 5.5mmD x 4mmL	44880	426052516AbutmentSup3B
MWD0093	4260525168616	WD Conical Healing Abutment 5.5mmD x 5mmL	44880	426052516AbutmentSup3B
MWD0094	4260525168623	WD Conical Healing Abutment 5.5mmD x 6mmL	44880	426052516AbutmentSup3B
Multi-Unit Healing Cap				
TMA-TGH	4260525163253	TMA Healing Cap	44880	426052516AbutmentSup3B
Grand Konisch™ Healing Abutment				
MGK0090	4260525169644	Grand Konisch™ Conical Healing Abutment 4.5mmD x 2mmL	44880	426052516AbutmentSup3B
MGK0091	4260525169651	Grand Konisch™ Conical Healing Abutment 4.5mmD x 3mmL	44880	426052516AbutmentSup3B
MGK0092	4260525169668	Grand Konisch™ Conical Healing Abutment 4.5mmD x 4mmL	44880	426052516AbutmentSup3B

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MGK0093	4260525169675	Grand Konisch™ Conical Healing Abutment 4.5mmD x 5mmL	44880	426052516AbutmentSup3B
MGK0094	4260525169682	Grand Konisch™ Conical Healing Abutment 4.5mmD x 6mmL	44880	426052516AbutmentSup3B
MGK0022	4260525169699	Grand Konisch™ Healing Abutment 4.5mmD x 2mmL	44880	426052516AbutmentSup3B
MGK0023	4260525169705	Grand Konisch™ Healing Abutment 4.5mmD x 3mmL	44880	426052516AbutmentSup3B
MGK0024	4260525169712	Grand Konisch™ Healing Abutment 4.5mmD x 4mmL	44880	426052516AbutmentSup3B
MGK0025	4260525169729	Grand Konisch™ Healing Abutment 4.5mmD x 5mmL	44880	426052516AbutmentSup3B
MGK0026	4260525169736	Grand Konisch™ Healing Abutment 4.5mmD x 6mmL	44880	426052516AbutmentSup3B
MGK0046	4260525169743	Grand Konisch™ Healing Abutment Slim 3.5mmD x 2mmL	44880	426052516AbutmentSup3B
MGK0047	4260525169750	Grand Konisch™ Healing Abutment Slim 3.5mmD x 3mmL	44880	426052516AbutmentSup3B
MGK0048	4260525169767	Grand Konisch™ Healing Abutment Slim 3.5mmD x 4mmL	44880	426052516AbutmentSup3B
MGK0049	4260525169774	Grand Konisch™ Healing Abutment Slim 3.5mmD x 5mmL	44880	426052516AbutmentSup3B
MGK0050	4260525169781	Grand Konisch™ Healing Abutment Slim 3.5mmD x 6mmL	44880	426052516AbutmentSup3B
MGK0095	4260525169798	Grand Konisch™ Conical Healing Abutment Slim 3.5mmD x 2mmL	44880	426052516AbutmentSup3B
MGK0096	4260525169804	Grand Konisch™ Conical Healing Abutment Slim 3.5mmD x 3mmL	44880	426052516AbutmentSup3B
MGK0097	4260525169811	Grand Konisch™ Conical Healing Abutment Slim 3.5mmD x 4mmL	44880	426052516AbutmentSup3B
MGK0098	4260525169828	Grand Konisch™ Conical Healing Abutment Slim 3.5mmD x 5mmL	44880	426052516AbutmentSup3B
MGK0099	4260525169835	Grand Konisch™ Conical Healing Abutment Slim 3.5mmD x 6mmL	44880	426052516AbutmentSup3B
MGK0046W	4260525169842	Grand Konisch™ Healing Abutment Wide 5.5mmD x 2mmL	44880	426052516AbutmentSup3B
MGK0047W	4260525169859	Grand Konisch™ Healing Abutment Wide 5.5mmD x 3mmL	44880	426052516AbutmentSup3B
MGK0048W	4260525169866	Grand Konisch™ Healing Abutment Wide 5.5mmD x 4mmL	44880	426052516AbutmentSup3B
MGK0049W	4260525169873	Grand Konisch™ Healing Abutment Wide 5.5mmD x 5mmL	44880	426052516AbutmentSup3B
MGK0050W	4260525169880	Grand Konisch™ Healing Abutment Wide 5.5mmD x 6mmL	44880	426052516AbutmentSup3B
MGK0095W	4260525169897	Grand Konisch™ Conical Healing Abutment Wide 5.5mmD x 2mmL	44880	426052516AbutmentSup3B
MGK0096W	4260525169903	Grand Konisch™ Conical Healing Abutment Wide 5.5mmD x 3mmL	44880	426052516AbutmentSup3B
MGK0097W	4260525169910	Grand Konisch™ Conical Healing Abutment Wide 5.5mmD x 4mmL	44880	426052516AbutmentSup3B
MGK0098W	4260525169927	Grand Konisch™ Conical Healing Abutment Wide 5.5mmD x 5mmL	44880	426052516AbutmentSup3B
MGK0099W	4260525169934	Grand Konisch™ Conical Healing Abutment Wide 5.5mmD x 6mmL	44880	426052516AbutmentSup3B
Cement Retained Abutments				
SD Straight Titanium Abutment				
SRA3N-3	4260525162416	Slim Titanium Abutment 3mm	44879	426052516AbutmentSup3B
SRA3N-6	4260525162423	Slim Titanium Abutment 6mm	44879	426052516AbutmentSup3B
SRA3N-8	4260525162430	Slim Titanium Abutment 8mm	44879	426052516AbutmentSup3B
SRA3	4260525162355	Straight Titanium Abutment - no end line	44879	426052516AbutmentSup3B
SRA3-1	4260525162362	Straight Titanium Abutment 1mm	44879	426052516AbutmentSup3B
SRA3-2	4260525162379	Straight Titanium Abutment 2mm	44879	426052516AbutmentSup3B
SRA3-3	4260525162386	Straight Titanium Abutment 3mm	44879	426052516AbutmentSup3B
SRA3-4	4260525162393	Straight Titanium Abutment 4mm	44879	426052516AbutmentSup3B
SRA3-5	4260525162409	Straight Titanium Abutment 5mm	44879	426052516AbutmentSup3B
TAL11.5	4260525162874	Straight Titanium Abutment Long 12.5mm	44879	426052516AbutmentSup3B

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SRA5	4260525162447	Straight Titanium Abutment 5mmD	44879	426052516AbutmentSup3B
MIH0010	4260525166773	IH Straight Abutment 1mmL	44879	426052516AbutmentSup3B
MIH0011	4260525166780	IH Straight Abutment 2mmL	44879	426052516AbutmentSup3B
MIH0012	4260525166797	IH Straight Abutment 3mmL	44879	426052516AbutmentSup3B
WPSRA	4260525163451	Wide Profile Titanium Abutment	44879	426052516AbutmentSup3B
MIH3945	4260525167169	Titanium Abutment for 4.5 mm Implant	44879	426052516AbutmentSup3B
IH Temporary Abutment (Straight Cylindrical Titanium Abutment)				
CAS2H	4260525161549	Straight Cylindrical Titanium Abutment 2mm - with hex	44879	426052516AbutmentSup3B
TAS2	4260525162881	Straight Cylindrical Titanium Abutment 2mm without hex	44880	426052516AbutmentSup3B
IH Fix-1™ Screw-in Abutment				
OPA	4260525161921	One Piece Screw-in Abutment	44879	426052516AbutmentSup3B
IH Angled Titanium Abutment				
PAB151	4260525161952	Angled Titanium Abutment 15Deg	44879	426052516AbutmentSup3B
PAB151L	4260525161990	Angled Titanium Abutment 15Deg long	44879	426052516AbutmentSup3B
MIH4017	4260525167176	IH Slim Angled Abutment 15° 1mm - No End Line	44879	426052516AbutmentSup3B
MIH4018	4260525167183	IH Slim Angled Abutment 15° 2mm - No End Line	44879	426052516AbutmentSup3B
MIH4019	4260525167190	IH Slim Angled Abutment 15° 3mm - No End Line	44879	426052516AbutmentSup3B
PAB151-1	4260525161969	Esthetic 1mm Angled Titanium Abutment 15Deg	44879	426052516AbutmentSup3B
PAB151-2	4260525161976	Esthetic 2mm Angled Titanium Abutment 15Deg	44879	426052516AbutmentSup3B
PAB151-3	4260525161983	Esthetic 3mm Angled Titanium Abutment 15Deg	44879	426052516AbutmentSup3B
PAB251	4260525162003	Angled Titanium Abutment 25Deg	44879	426052516AbutmentSup3B
PAB351	4260525162010	Angled Titanium Abutment 35Deg	44879	426052516AbutmentSup3B
ND Straight Abutment				
MND0010	4260525164694	ND Straight Slim Abutment - No End Line	44879	426052516AbutmentSup3B
MND0019	4260525164786	ND Straight Abutment 1mm	44879	426052516AbutmentSup3B
MND0011	4260525164700	ND Straight Abutment 2mm	44879	426052516AbutmentSup3B
MND0064	4260525165189	ND Straight Abutment 3mm	44879	426052516AbutmentSup3B
ND Temporary Abutment				
MND0044	4260525165028	ND Non Anti-rotation Temporary Abutment	44880	426052516AbutmentSup3B
MND0043	4260525165011	ND Anti-rotation Temporary Abutment	44880	426052516AbutmentSup3B
ND angled Abutment				
MND0018	4260525164779	ND Angled Abutment 15° - No End Line	44879	426052516AbutmentSup3B
MND0015	4260525164748	ND Angled Abutment 15° 1mm	44879	426052516AbutmentSup3B
MND0026	4260525164854	ND Angled Abutment 15° 2mm	44879	426052516AbutmentSup3B
MND0063	4260525165172	ND Angled Abutment 15° 3mm	44879	426052516AbutmentSup3B
MND0025	4260525164847	ND Angled Abutment 25° - No End Line	44879	426052516AbutmentSup3B
SD Straight Abutment				
MSD0020	4260525165844	SD Straight Slim Abutment - No End Line	44879	426052516AbutmentSup3B
MSD0012	4260525165769	SD Straight Abutment 1mm	44879	426052516AbutmentSup3B

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MSD0011	4260525165752	SD Straight Abutment 2mm	44879	426052516AbutmentSup3B
MSD0010	4260525165745	SD Straight Abutment 3mm	44879	426052516AbutmentSup3B
SD Temporary Abutment				
MSD0043	4260525166018	SD Anti-rotation Temporary Abutment	44880	426052516AbutmentSup3B
MSD0044	4260525166025	SD Free-rotation Temporary Abutment	44880	426052516AbutmentSup3B
SD Angled Abutment				
MSD0013	4260525165776	SD Angled Abutment 15° 1mm	44879	426052516AbutmentSup3B
MSD0014	4260525165783	SD Angled Abutment 15° 2mm	44879	426052516AbutmentSup3B
MSD0015	4260525165790	SD Angled Abutment 15° 3mm	44879	426052516AbutmentSup3B
WD Straight Abutment				
MWD0020	4260525168128	WD Straight Slim Abutment-No End Line	44879	426052516AbutmentSup3B
MWD0012	4260525168067	WD Straight Abutment 1mm	44879	426052516AbutmentSup3B
MWD0011	4260525168050	WD Straight Abutment 2mm	44879	426052516AbutmentSup3B
MWD0010	4260525168043	WD Straight Abutment 3mm	44879	426052516AbutmentSup3B
WD Temporary Abutment				
MWD0043	4260525168234	WD Anti-rotation Temporary Abutment	44880	426052516AbutmentSup3B
MWD0044	4260525168241	WD Free-rotation Temporary Abutment	44880	426052516AbutmentSup3B
WD Angled Abutment				
MWD0013	4260525168074	WD Angled Abutment 15° 1mm	44879	426052516AbutmentSup3B
MWD0014	4260525168081	WD Angled Abutment 15° 2mm	44879	426052516AbutmentSup3B
MWD0015	4260525168098	WD Angled Abutment 15° 3mm	44879	426052516AbutmentSup3B
Grand Konisch™ Straight Abutment				
MGK0010	4260525169941	Grand Konisch™ Straight Abutment 3mm	44879	426052516AbutmentSup3B
MGK0011	4260525169958	Grand Konisch™ Straight Abutment 2mm	44879	426052516AbutmentSup3B
MGK0012	4260525169965	Grand Konisch™ Straight Abutment 1mm	44879	426052516AbutmentSup3B
MGK0020	4260525169972	Grand Konisch™ Straight Slim Abutment - No End Line	44879	426052516AbutmentSup3B
MGK0010W	4260525165127	Grand Konisch™ Straight Abutment Wide 3mm	44879	426052516AbutmentSup3B
MGK0011W	4260525165134	Grand Konisch™ Straight Abutment Wide 2mm	44879	426052516AbutmentSup3B
MGK0012W	4260525165141	Grand Konisch™ Straight Abutment Wide 1mm	44879	426052516AbutmentSup3B
MGK1251	4260525165608	Grand Konisch™ Straight Abutment Long 12.5mm GH1	44879	426052516AbutmentSup3B
MGK1252	4260525165615	Grand Konisch™ Straight Abutment Long 12.5mm GH2	44879	426052516AbutmentSup3B
MGK1253	4260525165806	Grand Konisch™ Straight Abutment Long 12.5mm GH3	44879	426052516AbutmentSup3B
MGK1251W	4260525165813	Grand Konisch™ Straight Abutment Long Wide 12.5mm GH1	44879	426052516AbutmentSup3B
MGK1252W	4260525165868	Grand Konisch™ Straight Abutment Long Wide 12.5mm GH2	44879	426052516AbutmentSup3B
MGK1253W	4260525165875	Grand Konisch™ Straight Abutment Long Wide 12.5mm GH3	44879	426052516AbutmentSup3B
Grand Konisch™ Temporary Abutment				
MGK0036	4260525169989	Grand Konisch™ Engaging Temporary Abutment Slim 3.5mmD	44880	426052516AbutmentSup3B
MGK0037	4260525164755	Grand Konisch™ Non-Engaging Temporary Abutment Slim 3.5mmD	44880	426052516AbutmentSup3B
MGK0043	4260525164762	Grand Konisch™ Engaging Temporary Abutment 4.5mmD	44880	426052516AbutmentSup3B

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MGK0044	4260525164861	Grand Konisch™ Non-Engaging Temporary Abutment 4.5mmD	44880	426052516AbutmentSup3B
MGK0043W	4260525165158	Grand Konisch™ Engaging Temporary Abutment Wide 5.5mmD	44880	426052516AbutmentSup3B
MGK0044W	4260525165240	Grand Konisch™ Non-Engaging Temporary Abutment Wide 5.5mmD	44880	426052516AbutmentSup3B
Grand Konisch™ Angled Abutment				
MGK0013	4260525165882	Grand Konisch™ Angled Abutment 15° 1mm	44879	426052516AbutmentSup3B
MGK0014	4260525165899	Grand Konisch™ Angled Abutment 15° 2mm	44879	426052516AbutmentSup3B
MGK0015	4260525165905	Grand Konisch™ Angled Abutment 15° 3mm	44879	426052516AbutmentSup3B
MGK0013W	4260525165912	Grand Konisch™ Angled Abutment Wide 15° 1mm	44879	426052516AbutmentSup3B
MGK0014W	4260525165929	Grand Konisch™ Angled Abutment Wide 15° 2mm	44879	426052516AbutmentSup3B
MGK0015W	4260525166155	Grand Konisch™ Angled Abutment Wide 15° 3mm	44879	426052516AbutmentSup3B
MGK2515	4260525166162	Grand Konisch™ Angled Abutment 25° 1.5mm	44879	426052516AbutmentSup3B
MGK2530	4260525166179	Grand Konisch™ Angled Abutment 25° 3mm	44879	426052516AbutmentSup3B
MGK3515	4260525166186	Grand Konisch™ Angled Abutment 35° 1.5mm	44879	426052516AbutmentSup3B
MGK3530	4260525166193	Grand Konisch™ Angled Abutment 35° 3mm	44879	426052516AbutmentSup3B
MGK2515W	4260525166308	Grand Konisch™ Angled Abutment Wide 25° 1.5mm	44879	426052516AbutmentSup3B
MGK2530W	4260525166315	Grand Konisch™ Angled Abutment Wide 25° 3mm	44879	426052516AbutmentSup3B
MGK3515W	4260525166322	Grand Konisch™ Angled Abutment Wide 35° 1.5mm	44879	426052516AbutmentSup3B
MGK3530W	4260525166339	Grand Konisch™ Angled Abutment Wide 35° 3mm	44879	426052516AbutmentSup3B
Screw Retained Abutments				
IH Straight Multi-Unit Abutment				
TMI1	4260525163277	Straight Trans Mucosal Abutment 1mm	44879	426052516AbutmentSup3B
TMI2	4260525163284	Straight Trans Mucosal Abutment 2mm	44879	426052516AbutmentSup3B
TMI3	4260525163291	Straight Trans Mucosal Abutment 3mm	44879	426052516AbutmentSup3B
TMI4	4260525163307	Straight Trans Mucosal Abutment 4mm	44879	426052516AbutmentSup3B
TMI5	4260525163314	Straight Trans Mucosal Abutment 5mm	44879	426052516AbutmentSup3B
IH Angled Multi-Unit Abutment				
TMA17	4260525163031	Angled Trans Mucosal Abutment 17Deg 2mm	44879	426052516AbutmentSup3B
TMA1730	4260525163048	Angled Trans Mucosal Abutment 17Deg 3mm	44879	426052516AbutmentSup3B
TMA30	4260525163055	Angled Trans Mucosal Abutment 30Deg 3mm	44879	426052516AbutmentSup3B
TMA3040	4260525163062	Angled Trans Mucosal Abutment 30Deg 4mm	44879	426052516AbutmentSup3B
TMA45	4260525163079	Angled Trans Mucosal Abutment 45Deg 4mm	44879	426052516AbutmentSup3B
ND Straight Multi-Unit Abutment				
MND0032	4260525164908	ND Straight Multi Unit Abutment 1mm	44879	426052516AbutmentSup3B
MND0033	4260525164915	ND Straight Multi Unit Abutment 2mm	44879	426052516AbutmentSup3B
MND0034	4260525164922	ND Straight Multi Unit Abutment 3mm	44879	426052516AbutmentSup3B
MND3729	4260525165509	ND Straight Multi Unit Abutment 4mm	44879	426052516AbutmentSup3B
MND3730	4260525165516	ND Straight Multi Unitl Abutment 5mm	44879	426052516AbutmentSup3B
ND Angled Multi-Unit Abutment				
MND0035	4260525164939	ND Angled Multi Unit Abutment 17° L=3mm	44879	426052516AbutmentSup3B

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
MND0038	4260525164960	ND Angled Multi Unit Abutment 17° L=4mm	44879	426052516AbutmentSup3B
MND0036	4260525164946	ND Angled Multi Unit Abutment 30° L=3.5mm	44879	426052516AbutmentSup3B
MND0037	4260525164953	ND Angled Multi Unit Abutment 30° L=5mm	44879	426052516AbutmentSup3B
SD Straight Multi-Unit Abutment				
MSD0032	4260525165950	SD Straight Multi Unit Abutment 1mm	44879	426052516AbutmentSup3B
MSD0033	4260525165967	SD Straight Multi Unit Abutment 2mm	44879	426052516AbutmentSup3B
MSD0034	4260525165974	SD Straight Multi Unit Abutment 3mm	44879	426052516AbutmentSup3B
MSD3729	4260525166582	SD Straight Multi Unit Abutment 4 mm	44879	426052516AbutmentSup3B
MSD3730	4260525166599	SD Straight Multi Unit Abutment 5 mm	44879	426052516AbutmentSup3B
SD Angled Multi-Unit Abutment				
MSD3734	4260525166605	SD Angled Multi Unit Abutment 17° 2.5mm	44879	426052516AbutmentSup3B
MSD3737	4260525166629	SD Angled Multi Unit Abutment 17° 3.5mm	44879	426052516AbutmentSup3B
MSD3735	4260525166612	SD Angled Multi Unit Abutment 30° 3mm	44879	426052516AbutmentSup3B
MSD3738	4260525166636	SD Angled Multi Unit Abutment 30° 4mm	44879	426052516AbutmentSup3B
WD Straight Multi-Unit Abutment				
MWD3731	4260525168838	WD Straight Multi Unit Abutment 1mm	44879	426052516AbutmentSup3B
MWD3732	4260525168845	WD Straight Multi Unit Abutment 2mm	44879	426052516AbutmentSup3B
MWD3733	4260525168852	WD Straight Multi Unit Abutment 3mm	44879	426052516AbutmentSup3B
MWD3729	4260525168814	WD Straight Multi Unit Abutment 4mm	44879	426052516AbutmentSup3B
MWD3730	4260525168821	WD Straight Multi Unit Abutment 5mm	44879	426052516AbutmentSup3B
WD Angled Multi-Unit Abutment				
MWD3734	4260525168869	WD Angled Multi Unit Abutment 17° 2.5mm	44879	426052516AbutmentSup3B
MWD3737	4260525168883	WD Angled Multi Unit Abutment 17° 3.5mm	44879	426052516AbutmentSup3B
MWD3735	4260525168876	WD Angled Multi Unit Abutment 30° 3mm	44879	426052516AbutmentSup3B
MWD3738	4260525168890	WD Angled Multi Unit Abutment 30° 4mm	44879	426052516AbutmentSup3B
Grand Konisch™ Straight Multi-Unit Abutment				
MGK0032	4260525166988	Grand Konisch™ Straight Multi Unit Abutment 1mm	44879	426052516AbutmentSup3B
MGK0033	4260525166995	Grand Konisch™ Straight Multi Unit Abutment 2mm	44879	426052516AbutmentSup3B
MGK0034	4260525167008	Grand Konisch™ Straight Multi Unit Abutment 3mm	44879	426052516AbutmentSup3B
MGK3729	4260525167015	Grand Konisch™ Straight Multi Unit Abutment 4mm	44879	426052516AbutmentSup3B
MGK3730	4260525167022	Grand Konisch™ Straight Multi Unit Abutment 5mm	44879	426052516AbutmentSup3B
Grand Konisch™ Angled Multi-Unit Abutment				
MGK3734	4260525167060	Grand Konisch™ Angled Multi Unit Abutment 17° 2.5mm	44879	426052516AbutmentSup3B
MGK3735	4260525167121	Grand Konisch™ Angled Multi Unit Abutment 30° 3mm	44879	426052516AbutmentSup3B
MGK3737	4260525167138	Grand Konisch™ Angled Multi Unit Abutment 17° 3.5mm	44879	426052516AbutmentSup3B
MGK3738	4260525167145	Grand Konisch™ Angled Multi Unit Abutment 30° 4mm	44879	426052516AbutmentSup3B
MGK3736	4260525167152	Grand Konisch™ Angled Multi Unit Abutment 45° 4mm	44879	426052516AbutmentSup3B
Multi-Unit Temporary Abutment				
TMA-TTC	4260525163260	TMA Titanium Temporary Copying	44880	426052516AbutmentSup3B

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IH Flat Connection Abutment				
FLAT4502	4260525163659	Abutment 2mm Flat Connection	44879	426052516AbutmentSup3B
FLAT4504	4260525163666	Abutment 4mm Flat Connection	44879	426052516AbutmentSup3B
ND Flat Connection Abutment				
MND0030	4260525164885	ND Flat Connection Abutment 2mm	44879	426052516AbutmentSup3B
MND0031	4260525164892	ND Flat Connection Abutment 4mm	44879	426052516AbutmentSup3B
SD Flat Connection Abutment				
MSD0030	4260525165936	SD Flat Connection Abutment 2mm	44879	426052516AbutmentSup3B
MSD0031	4260525165943	SD Flat Connection Abutment 4mm	44879	426052516AbutmentSup3B
WD Flat Connection Abutment				
MWD0030	4260525168210	WD Flat Connection Abutment 2mm	44880	426052516AbutmentSup3B
MWD0031	4260525168227	WD Flat Connection Abutment 4mm	44880	426052516AbutmentSup3B
Grand Konisch™ Flat Connection Abutment				
MGK0030	4260525167466	Grand Konisch™ Flat Connection Abutment 2mm	44879	426052516AbutmentSup3B
MGK0031	4260525167473	Grand Konisch™ Flat Connection Abutment 4mm	44879	426052516AbutmentSup3B
Flat Connection Accessories				
FLAT6013	4260525163710	Titanium Gluing Ring Flat Connection	44879	426052516AbutmentSup3B
FLAT5515	4260525163680	Temporary Cylinder Sleeve Flat Connection	44880	426052516AbutmentSup3B
Cement or Screw Retained Abutments (UCLA Abutments)				
IH Titanium / Plastic Abutment (TitanFix)				
CATPE	4260525161556	Titanium/Plastic Abutment With Hex	44879	426052516AbutmentSup3B
CATPNE	4260525161563	Titanium/Plastic Abutment Without Hex	44879	426052516AbutmentSup3B
ND Titanium / Plastic Abutment (TitanFix)				
MND3095	4260525165455	ND Anti-rotation Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
MND3097	4260525165462	ND Free-rotation Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
SD Titanium / Plastic Abutment (TitanFix)				
MSD3095	4260525166513	SD Anti-rotation Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
MSD3097	4260525166520	SD Free-rotation Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
WD Titanium / Plastic Abutment (TitanFix)				
MWD3095	4260525168715	WD Anti-rotation Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
MWD3097	4260525168722	WD Free-rotation Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
Grand Konisch™ Titanium / Plastic Abutment (TitanFix)				
MGK3095	4260525165097	Grand Konisch™ Engaging Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
MGK3097	4260525165103	Grand Konisch™ Non-Engaging Titanium/Plastic Abutment	44879	426052516AbutmentSup3B
MGK3095W	4260525165264	Grand Konisch™ Engaging Titanium/Plastic Abutment Wide	44879	426052516AbutmentSup3B
MGK3097W	4260525165295	Grand Konisch™ Non-Engaging Titanium/Plastic Abutment Wide	44879	426052516AbutmentSup3B
IH Gold / Plastic Abutment (GoldFix)				
CAGPE	4260525161525	Gold Alloy Abutment With Hex	44879	426052516AbutmentSup3B
IH Cobalt Chrome / Plastic Abutment (CoCrFix)				

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
MIH3094	4260525167039	IH Anti-Rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
MIH3100	4260525167046	IH Free-Rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
ND Cobalt Chrome / Plastic Abutment (CoCrFix)				
MND3094	4260525165448	ND Anti-rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
MND3100	4260525165479	ND Free-rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
SD Cobalt Chrome / Plastic Abutment (CoCrFix)				
MSD3094	4260525166506	SD Anti-rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
MSD3100	4260525166537	SD Free-rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
WD Cobalt Chrome / Plastic Abutment (CoCrFix)				
MWD3094	4260525168708	WD Anti-rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
MWD3100	4260525168739	WD Free-rotation Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
Grand Konisch™ Cobalt Chrome/ Plastic Abutment (CoCrFix)				
MGK3094	4260525164878	Grand Konisch™ Engaging Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
MGK3100	4260525165110	Grand Konisch™ Non-Engaging Cobalt Chrome/Plastic Abutment	44879	426052516AbutmentSup3B
MGK3094W	4260525165257	Grand Konisch™ Engaging Cobalt Chrome/Plastic Abutment Wide	44879	426052516AbutmentSup3B
MGK3100W	4260525165585	Grand Konisch™ Non-Engaging Cobalt Chrome/Plastic Abutment Wide	44879	426052516AbutmentSup3B
Prosthetic Components for CAD/CAM				
Multi-Unit Cementing Cone				
MMU0010	4260525168012	MU Cementing Cone	44879	426052516AbutmentSup3B
IH Ti Base				
MIH1404	4260525166872	IH Ti Base Anti-Rotation	44879	426052516AbutmentSup3B
MIH1408	4260525166889	IH Ti Base Free-Rotation	44879	426052516AbutmentSup3B
MIH1417	4260525166919	IH Ti Base Angular Anti-Rotation	44879	426052516AbutmentSup3B
ND Ti Base				
MND1004	4260525165394	ND Fix Konisch™ Ti Base anti-rotation	44879	426052516AbutmentSup3B
MND1008	4260525165400	ND Fix Konisch™ Ti Base free-rotation	44879	426052516AbutmentSup3B
MND1017	4260525165417	ND Fix Konisch™ Ti Base Angular anti-rotation	44879	426052516AbutmentSup3B
SD Ti Base				
MSD1204	4260525166452	SD Fix Konisch™ Ti Base anti-rotation	44879	426052516AbutmentSup3B
MSD1208	4260525166469	SD Fix Konisch™ Ti Base free-rotation	44879	426052516AbutmentSup3B
MSD1217	4260525166490	SD Fix Konisch™ Ti Base Angular anti-rotation	44879	426052516AbutmentSup3B
WD Ti Base				
MWD1304	4260525168654	WD Fix Konisch™ Ti Base anti-rotation	44879	426052516AbutmentSup3B
MWD1308	4260525168661	WD Fix Konisch™ Ti Base free-rotation	44879	426052516AbutmentSup3B
MWD1317	4260525168692	WD Fix Konisch™ Ti Base Angular anti-rotation	44879	426052516AbutmentSup3B
Grand Konisch™ Ti Base				
TBMGK07411	4260525167480	Ti Base Grand Konisch™ Abutment, RH 4mm GH 1mm Engaged	44879	426052516AbutmentSup3B
TBMGK07611	4260525167497	Ti Base Grand Konisch™ Abutment, RH 6mm GH 1mm Engaged	44879	426052516AbutmentSup3B
TBMGK07811	4260525167503	Ti Base Grand Konisch™ Abutment, RH 8mm GH 1mm Engaged	44879	426052516AbutmentSup3B

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
TBMGK07421	4260525167510	Ti Base Grand Konisch™ Abutment, RH 4mm GH 2mm Engaged	44879	426052516AbutmentSup3B
TBMGK07621	4260525167527	Ti Base Grand Konisch™ Abutment, RH 6mm GH 2mm Engaged	44879	426052516AbutmentSup3B
TBMGK07821	4260525167534	Ti Base Grand Konisch™ Abutment, RH 8mm GH 2mm Engaged	44879	426052516AbutmentSup3B
TBMGK07431	4260525167541	Ti Base Grand Konisch™ Abutment, RH 4mm GH 3mm Engaged	44879	426052516AbutmentSup3B
TBMGK07631	4260525167558	Ti Base Grand Konisch™ Abutment, RH 6mm GH 3mm Engaged	44879	426052516AbutmentSup3B
TBMGK07831	4260525167565	Ti Base Grand Konisch™ Abutment, RH 8mm GH 3mm Engaged	44879	426052516AbutmentSup3B
TBMGK07441	4260525167572	Ti Base Grand Konisch™ Abutment, RH 4mm GH 4mm Engaged	44879	426052516AbutmentSup3B
TBMGK07641	4260525167589	Ti Base Grand Konisch™ Abutment, RH 6mm GH 4mm Engaged	44879	426052516AbutmentSup3B
TBMGK07841	4260525167596	Ti Base Grand Konisch™ Abutment, RH 8mm GH 4mm Engaged	44879	426052516AbutmentSup3B
TBMGK07412	4260525167602	Ti Base Grand Konisch™ Abutment, RH 4mm GH 1mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07612	4260525167619	Ti Base Grand Konisch™ Abutment, RH 6mm GH 1mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07812	4260525167626	Ti Base Grand Konisch™ Abutment, RH 8mm GH 1mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07422	4260525167633	Ti Base Grand Konisch™ Abutment, RH 4mm GH 2mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07622	4260525167640	Ti Base Grand Konisch™ Abutment, RH 6mm GH 2mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07822	4260525167657	Ti Base Grand Konisch™ Abutment, RH 8mm GH 2mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07432	4260525167664	Ti Base Grand Konisch™ Abutment, RH 4mm GH 3mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07632	4260525167671	Ti Base Grand Konisch™ Abutment, RH 6mm GH 3mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07832	4260525167688	Ti Base Grand Konisch™ Abutment, RH 8mm GH 3mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07442	4260525167695	Ti Base Grand Konisch™ Abutment, RH 4mm GH 4mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07642	4260525167701	Ti Base Grand Konisch™ Abutment, RH 6mm GH 4mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07842	4260525167718	Ti Base Grand Konisch™ Abutment, RH 8mm GH 4mm Non-Engaged	44879	426052516AbutmentSup3B
TBMGK07413	4260525167725	Ti Base Grand Konisch™ Abutment, RH 4mm GH 1mm Angular	44879	426052516AbutmentSup3B
TBMGK07613	4260525167732	Ti Base Grand Konisch™ Abutment, RH 6mm GH 1mm Angular	44879	426052516AbutmentSup3B
TBMGK07813	4260525167749	Ti Base Grand Konisch™ Abutment, RH 8mm GH 1mm Angular	44879	426052516AbutmentSup3B
TBMGK07423	4260525167756	Ti Base Grand Konisch™ Abutment, RH 4mm GH 2mm Angular	44879	426052516AbutmentSup3B
TBMGK07623	4260525167763	Ti Base Grand Konisch™ Abutment, RH 6mm GH 2mm Angular	44879	426052516AbutmentSup3B
TBMGK07823	4260525167770	Ti Base Grand Konisch™ Abutment, RH 8mm GH 2mm Angular	44879	426052516AbutmentSup3B
TBMGK07433	4260525167787	Ti Base Grand Konisch™ Abutment, RH 4mm GH 3mm Angular	44879	426052516AbutmentSup3B
TBMGK07633	4260525167794	Ti Base Grand Konisch™ Abutment, RH 6mm GH 3mm Angular	44879	426052516AbutmentSup3B
TBMGK07833	4260525167800	Ti Base Grand Konisch™ Abutment, RH 8mm GH 3mm Angular	44879	426052516AbutmentSup3B
TBMGK07443	4260525167824	Ti Base Grand Konisch™ Abutment, RH 4mm GH 4mm Angular	44879	426052516AbutmentSup3B
TBMGK07643	4260525167848	Ti Base Grand Konisch™ Abutment, RH 6mm GH 4mm Angular	44879	426052516AbutmentSup3B
TBMGK07843	4260525167855	Ti Base Grand Konisch™ Abutment, RH 8mm GH 4mm Angular	44879	426052516AbutmentSup3B
TBMGK07411W	4260525167862	Ti Base Grand Konisch™ Abutment, RH 4mm GH 1mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07611W	4260525167879	Ti Base Grand Konisch™ Abutment, RH 6mm GH 1mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07811W	4260525167909	Ti Base Grand Konisch™ Abutment, RH 8mm GH 1mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07421W	4260525167916	Ti Base Grand Konisch™ Abutment, RH 4mm GH 2mm Engaged Wide	44879	426052516AbutmentSup3B

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TBMGK07621W	4260525167923	Ti Base Grand Konisch™ Abutment, RH 6mm GH 2mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07821W	4260525167930	Ti Base Grand Konisch™ Abutment, RH 8mm GH 2mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07431W	4260525167947	Ti Base Grand Konisch™ Abutment, RH 4mm GH 3mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07631W	4260525167954	Ti Base Grand Konisch™ Abutment, RH 6mm GH 3mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07831W	4260525167961	Ti Base Grand Konisch™ Abutment, RH 8mm GH 3mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07441W	4260525167978	Ti Base Grand Konisch™ Abutment, RH 4mm GH 4mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07641W	4260525168104	Ti Base Grand Konisch™ Abutment, RH 6mm GH 4mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07841W	4260525168111	Ti Base Grand Konisch™ Abutment, RH 8mm GH 4mm Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07412W	4260525168197	Ti Base Grand Konisch™ Abutment, RH 4mm GH 1mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07612W	4260525168203	Ti Base Grand Konisch™ Abutment, RH 6mm GH 1mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07812W	4260525168371	Ti Base Grand Konisch™ Abutment, RH 8mm GH 1mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07422W	4260525168388	Ti Base Grand Konisch™ Abutment, RH 4mm GH 2mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07622W	4260525168395	Ti Base Grand Konisch™ Abutment, RH 6mm GH 2mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07822W	4260525168401	Ti Base Grand Konisch™ Abutment, RH 8mm GH 2mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07432W	4260525168418	Ti Base Grand Konisch™ Abutment, RH 4mm GH 3mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07632W	4260525168500	Ti Base Grand Konisch™ Abutment, RH 6mm GH 3mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07832W	4260525168517	Ti Base Grand Konisch™ Abutment, RH 8mm GH 3mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07442W	4260525168524	Ti Base Grand Konisch™ Abutment, RH 4mm GH 4mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07642W	4260525168531	Ti Base Grand Konisch™ Abutment, RH 6mm GH 4mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07842W	4260525168548	Ti Base Grand Konisch™ Abutment, RH 4mm GH 2mm Non-Engaged Wide	44879	426052516AbutmentSup3B
TBMGK07413W	4260525168555	Ti Base Grand Konisch™ Abutment, RH 4mm GH 1mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07613W	4260525168630	Ti Base Grand Konisch™ Abutment, RH 6mm GH 1mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07813W	4260735770005	Ti Base Grand Konisch™ Abutment, RH 8mm GH 1mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07423W	4260735770012	Ti Base Grand Konisch™ Abutment, RH 4mm GH 2mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07623W	4260735770029	Ti Base Grand Konisch™ Abutment, RH 6mm GH 2mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07823W	4260735770036	Ti Base Grand Konisch™ Abutment, RH 8mm GH 2mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07433W	4260735770043	Ti Base Grand Konisch™ Abutment, RH 4mm GH 3mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07633W	4260735770050	Ti Base Grand Konisch™ Abutment, RH 6mm GH 3mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07833W	4260735770067	Ti Base Grand Konisch™ Abutment, RH 8mm GH 3mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07443W	4260735770074	Ti Base Grand Konisch™ Abutment, RH 4mm GH 4mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07643W	4260735770081	Ti Base Grand Konisch™ Abutment, RH 6mm GH 4mm Angular Wide	44879	426052516AbutmentSup3B
TBMGK07843W	4260735770098	Ti Base Grand Konisch™ Abutment, RH 8mm GH 4mm Angular Wide	44879	426052516AbutmentSup3B
IH Ti Blank				
MIH1411	4260525166896	IH Pre Milled MDTK Ti Blank D11.5mm	44879	426052516AbutmentSup3B

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
MIH1415	4260525166902	IH TPre Milled MDTK Ti Blank D15.8mm	44879	426052516AbutmentSup3B
ND Ti Blank				
MND1111	4260525165424	ND Fix Konisch™ Pre Milled MDTK Ti Blank D11.5mm	44879	426052516AbutmentSup3B
MND1115	4260525165431	ND Fix Konisch™ Pre Milled MDTK Ti Blank D15.8mm	44879	426052516AbutmentSup3B
SD Ti Blank				
MSD1211	4260525166476	SD Fix Konisch™ Pre Milled MDTK Ti Blank D11.5mm	44879	426052516AbutmentSup3B
MSD1215	4260525166483	SD Fix Konisch™ Pre Milled MDTK Ti Blank D15.8mm	44879	426052516AbutmentSup3B
WD Ti Blank				
MWD1311	4260525168678	WD Fix Konisch™ Pre Milled MDTK Ti Blank D11.5mm	44879	426052516AbutmentSup3B
MWD1315	4260525168685	WD Fix Konisch™ Pre Milled MDTK Ti Blank D15.8mm	44879	426052516AbutmentSup3B
Grand Konisch™ Ti Blank				
MGK1211	4260735770104	Grand Konisch™ Ti Pre Milled MDTK Abutment Blank D11.5mm	44879	426052516AbutmentSup3B
MGK1215	4260735770111	Grand Konisch™ Ti Pre Milled MDTK Abutment Blank D15.8mm	44879	426052516AbutmentSup3B
Overdenture's Attachments				
IH Ball Attachment				
TMIB1-P3	4260525163345	Ball Attachment 1mm w/hex	44879	426052516AbutmentSup3B
TMIB2-P3	4260525163369	Ball Attachment 2mm w/hex	44879	426052516AbutmentSup3B
TMIB3-P3	4260525163383	Ball Attachment 3mm w/hex	44879	426052516AbutmentSup3B
MIH2864	4260525166957	IH Ball Attachment 4mm w/Hex	44879	426052516AbutmentSup3B
TMIB5-P3	4260525163420	Ball Attachment 5mm w/hex	44879	426052516AbutmentSup3B
TMIB6-P3	4260525163437	Ball Attachment 6mm w/hex	44879	426052516AbutmentSup3B
TMIB0.5	4260525163321	Ball Attachment 0.5mm	44879	426052516AbutmentSup3B
TMIB1	4260525163338	Ball Attachment 1mm	44879	426052516AbutmentSup3B
TMIB2	4260525163352	Ball Attachment 2mm	44879	426052516AbutmentSup3B
TMIB3	4260525163376	Ball Attachment 3mm	44879	426052516AbutmentSup3B
TMIB4	4260525163390	Ball Attachment 4mm	44879	426052516AbutmentSup3B
TMIB5	4260525163413	Ball Attachment 5mm	44879	426052516AbutmentSup3B
ND Ball Attachment				
MND0020	4260525164793	ND Ball Attachment 0.5mm	44879	426052516AbutmentSup3B
MND0021	4260525164809	ND Ball Attachment 1mm	44879	426052516AbutmentSup3B
MND0022	4260525164816	ND Ball Attachment 2mm	44879	426052516AbutmentSup3B
MND0023	4260525164823	ND Ball Attachment 3mm	44879	426052516AbutmentSup3B
MND0024	4260525164830	ND Ball Attachment 4mm	44879	426052516AbutmentSup3B
MND0084	4260525165271	ND Ball Attachment 8 mm	44879	426052516AbutmentSup3B
MND0085	4260525165288	ND Ball Attachment 9 mm	44879	426052516AbutmentSup3B
SD Ball Attachment				
MSD0051	4260525166094	SD Ball Attachment 0.5mm	44879	426052516AbutmentSup3B
MSD0052	4260525166100	SD Ball Attachment 1mm	44879	426052516AbutmentSup3B
MSD0053	4260525166117	SD Ball Attachment 2mm	44879	426052516AbutmentSup3B

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
MSD0054	4260525166124	SD Ball Attachment 3mm	44879	426052516AbutmentSup3B
MSD0055	4260525166131	SD Ball Attachment 4mm	44879	426052516AbutmentSup3B
MSD0056	4260525166148	SD Ball Attachment 5mm	44879	426052516AbutmentSup3B
WD Ball Attachment				
MWD0051	4260525168319	WD Ball Attachment 0.5mm	44879	426052516AbutmentSup3B
MWD0052	4260525168326	WD Ball Attachment 1mm	44879	426052516AbutmentSup3B
MWD0053	4260525168333	WD Ball Attachment 2mm	44879	426052516AbutmentSup3B
MWD0054	4260525168340	WD Ball Attachment 3mm	44879	426052516AbutmentSup3B
MWD0055	4260525168357	WD Ball Attachment 4mm	44879	426052516AbutmentSup3B
MWD0056	4260525168364	WD Ball Attachment 5mm	44879	426052516AbutmentSup3B
Grand Konisch™ Ball Attachment Abutment				
MGK0051	4260525167237	Grand Konisch™ Ball Attachment 0.5mm	44879	426052516AbutmentSup3B
MGK0052	4260525167244	Grand Konisch™ Ball Attachment 1mm	44879	426052516AbutmentSup3B
MGK0053	4260525167299	Grand Konisch™ Ball Attachment 2mm	44879	426052516AbutmentSup3B
MGK0054	4260525167381	Grand Konisch™ Ball Attachment 3mm	44879	426052516AbutmentSup3B
MGK0055	4260525167428	Grand Konisch™ Ball Attachment 4mm	44879	426052516AbutmentSup3B
MGK0056	4260525167459	Grand Konisch™ Ball Attachment 5mm	44879	426052516AbutmentSup3B
Ball Caps				
NC01	4260525161907	Plastic Ball Cap white	44880	426052516AbutmentSup3B
NCP	4260525161914	Plastic Ball Cap Pink	44880	426052516AbutmentSup3B
Metal Housing				
HOT	4260525161846	Ball Cap Titanium	44880	426052516AbutmentSup3B
Screws				
Implant Cover screws				
CSS	4260525161570	Implant Cover Screw	44880	426052516AbutmentSup3B
MND0002	4260525164618	ND Implant Cover Screw	44880	426052516AbutmentSup3B
MND0073	4260525165226	ND Conical Implant Cover Screw	44880	426052516AbutmentSup3B
MSD0021	4260525165851	SD Implant Cover Screw	44880	426052516AbutmentSup3B
MSD0073	4260525166285	SD Conical Implant Cover Screw	44880	426052516AbutmentSup3B
MWD0021	4260525168135	WD Implant Cover Screw	44880	426052516AbutmentSup3B
MWD0073	4260525168487	WD Conical Implant Cover Screw	44880	426052516AbutmentSup3B
MGK0073	4260525169637	Grand Konisch™ Conical Implant Cover Screw	44880	426052516AbutmentSup3B
IH Abutment Screw				
SRAS	4260525162454	Prosthetic Screw	61647	426052516AbutmentSup3B
SRAS2	4260525162478	Short Prosthetic Screw	61647	426052516AbutmentSup3B
PAS	4260525162041	Screw for Angled Titanium Abutment	61647	426052516AbutmentSup3B
MIH3424	4260525167084	IH Screw for Esthetic Connection	61647	426052516AbutmentSup3B
MIH3405	4260525167053	IH Screw for Esthetic Connection Abutment 0.5mm	61647	426052516AbutmentSup3B
CAS1.5	4260525161532	Screw For Esthetic Connection Abutment 1.5mm	61647	426052516AbutmentSup3B

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
MIH3420	4260525167077	IH Screw for Esthetic Connection Abutment 2mm	61647	426052516AbutmentSup3B
MIH3460	4260525167114	IH Screw for Connection Abutment	61647	426052516AbutmentSup3B
IH Multi-Unit Retaining Screw				
SRAS3	4260525162485	Retaining Screw for Angled TMA	61647	426052516AbutmentSup3B
TMA-SRAS1	4260525163161	Retaining Screw for TMA 1mm	61647	426052516AbutmentSup3B
TMA-SRAS2	4260525163178	Retaining Screw for TMA 2mm	61647	426052516AbutmentSup3B
TMA-SRAS3	4260525163185	Retaining Screw for TMA 3mm	61647	426052516AbutmentSup3B
TMA-SRAS4	4260525163192	Retaining Screw for TMA 4mm	61647	426052516AbutmentSup3B
TMA-SRAS5	4260525163208	Retaining Screw for TMA 5mm	61647	426052516AbutmentSup3B
ND Abutment Screw				
MND0001	4260525164601	ND Abutment Screw	61647	426052516AbutmentSup3B
ND Multi-Unit Retaining Screw				
MND0042	4260525165004	ND Retaining Screw for Angled MU	61647	426052516AbutmentSup3B
MND0039	4260525164977	ND Retaining Screw for MU 1mm	61647	426052516AbutmentSup3B
MND0040	4260525164984	ND Retaining Screw for MU 2mm	61647	426052516AbutmentSup3B
MND0041	4260525164991	ND Retaining Screw for MU 3mm	61647	426052516AbutmentSup3B
MND3409	4260525165486	ND Retaining Screw for MU 4mm	61647	426052516AbutmentSup3B
MND3412	4260525165493	ND Retaining Screw for MU 5mm	61647	426052516AbutmentSup3B
SD Abutment Screw				
MSD0001	4260525165707	SD Abutment Screw	61647	426052516AbutmentSup3B
SD Multi-Unit Retaining Screw				
MSD3403	4260525166551	SD Retaining Screw for Angled MU	61647	426052516AbutmentSup3B
MSD0039	4260525165981	SD Retaining Screw for MU 1mm	61647	426052516AbutmentSup3B
MSD0040	4260525165998	SD Retaining Screw for MU 2mm	61647	426052516AbutmentSup3B
MSD0041	4260525166001	SD Retaining Screw for MU 3mm	61647	426052516AbutmentSup3B
MSD3409	4260525166568	SD Retaining Screw for MU 4mm	61647	426052516AbutmentSup3B
MSD3412	4260525166575	SD Retaining Screw for MU 5mm	61647	426052516AbutmentSup3B
WD Abutment Screw				
MWD0001	4260525168029	WD Abutment Screw	61647	426052516AbutmentSup3B
WD Multi-Unit Retaining Screw				
MWD3403	4260525168753	WD Retaining Screw for Angled MU	61647	426052516AbutmentSup3B
MWD3406	4260525168760	WD Retaining Screw for MU 1mm	61647	426052516AbutmentSup3B
MWD3407	4260525168777	WD Retaining Screw for MU 2mm	61647	426052516AbutmentSup3B
MWD3408	4260525168784	WD Retaining Screw for MU 3mm	61647	426052516AbutmentSup3B
MWD3409	4260525168791	WD Retaining Screw for MU 4mm	61647	426052516AbutmentSup3B
MWD3412	4260525168807	WD Retaining Screw for MU 5mm	61647	426052516AbutmentSup3B
Grand Konisch™ Abutment Screw				
MGK0001	4260525166940	Grand Konisch™ Abutment Screw M1.6	44880	426052516AbutmentSup3B
MGK0002	4260525166971	Grand Konisch™ Short Abutment Screw M1.6	44880	426052516AbutmentSup3B

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Cat. Number	UDI-DI Number	Description	GMDN	Basic UDI-DI
Grand Konisch™ Multi-Unit Retaining Screw				
MGK0039	4260525166346	Grand Konisch™ Retaining Screw for MU 1mm	61647	426052516AbutmentSup3B
MGK0040	4260525166438	Grand Konisch™ Retaining Screw for MU 2mm	61647	426052516AbutmentSup3B
MGK0041	4260525166803	Grand Konisch™ Retaining Screw for MU 3mm	61647	426052516AbutmentSup3B
MGK3409	4260525166810	Grand Konisch™ Retaining Screw for MU 4mm	61647	426052516AbutmentSup3B
MGK3412	4260525166926	Grand Konisch™ Retaining Screw for MU 5mm	61647	426052516AbutmentSup3B
MGK3403	4260525166933	Grand Konisch™ Retaining Screw for Angled MU	61647	426052516AbutmentSup3B
Multi-Unit Prosthetic Screw				
TPS	4260525163444	TMA Prosthetic Screw	61647	426052516AbutmentSup3B
Flat Connection Screw				
FLAT6015	4260525163734	Titanium Retaining Screw Flat Connection	61647	426052516AbutmentSup3B

-- END OF PRODUCT LIST –

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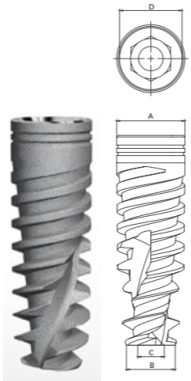
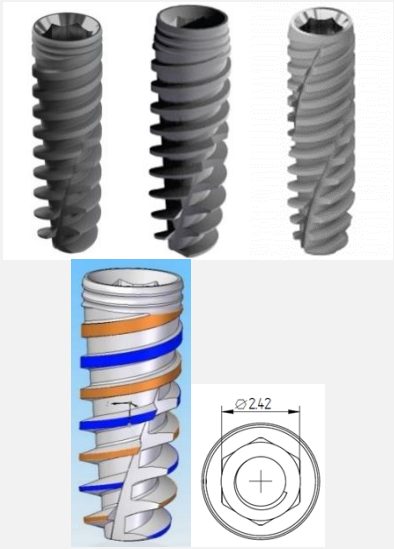
Appendix B – Summery of Medigma's Dental Implant system and Similar Devices

Product / Feature	Similar Device #1 – Spiral™ (SPI) Implant by Alpha-Bio Tec	Medigma's Mars™ and FixTite™ dental implants	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	Alpha-Bio Tec implants are intended for rehabilitating fully or partially edentulous patients. Dental implants are intended to be used in a manner that they will integrate the bone (osseointegration).	Medigma's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.	= Same. All products have the same intended use, Medigma has more restricted indication for narrow implants.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	= Same
Surface treatment	Sandblasting and acid etching surface treatment	AB/AE (alumina oxide blasting / acid etching)	= Same
Basic design	Spiral, tapered with double threads	Spiral, tapered, double-lead thread	= Same
Implant-abutment connection	Internal hex	Internal hex	= Same
Diameters	3.3, 3.75, 4.2, 5, 6	3.5, 3.75, 4.2, 5, 6	= Same
Lengths	8, 10, 11.5, 13, 16 (for 3.3 – 5mmD), 8, 10, 11.5, 13 (for 6mmD)	8, 10, 11.5, 13, 16, 18 (for 3.5-3.75mmD) 6.25, 8, 10, 11.5, 13, 16, 18 (for 4.2mmD) 6.25, 8, 10, 11.5, 13, 16 (for 5mmD) 6.25, 8, 10, 11.5, 13 (for 6mmD)	✓ Better. Medigma has wider variety of dimensions verified and validated by pre-clinical testing.
Sterility	Sterile using gamma radiation	Sterile using gamma radiation	= Same
Prosthetic components	Healing abutments. Cement-retained abutments (straight and angulated: 15°, 25°). Screw-retained abutments (straight and angular: 17°, 30°). Overdenture restorations (straight and angular).	Healing abutments Cement-retained abutments (straight and angulated: 15°, 25°, 35° for IH). Screw-retained abutments (straight and angulated: 17°, 30° and 45° for IH). Overdenture restorations (straight). CAD/CAM components (Ti Bases, Ti Pre-Milled Abutment Blanks).	✓ Better. Medigma has wider variety of prosthetic solutions verified and validated by pre-clinical testing
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design

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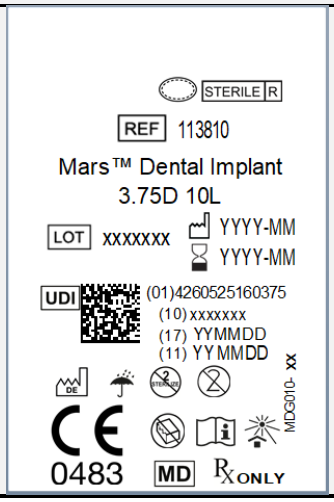
Product / Feature	Similar Device #1 – Spiral™ (SPI) Implant by Alpha-Bio Tec	Medigma's Mars™ and FixTite™ dental implants	Medigma's Dental Implants approach [=, ✓, ✖]
Label			= Same

Product / Feature	Similar Device #2 – I5 Conical Implant by A.B. Dental	Medigma's Fix Konisch™ (ND, SD and WD) and Grand Konisch™ dental implants	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	A.B. Dental Devices' implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. Implants for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Medigma's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. Narrow implants identified as Fix Konisch™ ND (3.0mmD) are indicated for use only in replacement of maxillary lateral incisors and mandibular lateral and central incisors.	= Same. All products have the same intended use, Medigma has more restricted indication for narrow implants.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)	= Same
Surface treatment	Special blasting with calcium phosphate	Calcium Phosphate blasting	= Same
Basic design	Spiral, tapered with double threads	Spiral, tapered, double-lead thread	= Same
Implant-abutment connection	Internal hex	Conical hex in Fix Konisch™ ND, SD and WD implants, Conical star in Grand Konisch™ implants.	= Same. Implant-abutment connection is verified and validated with fatigue test per ISO 14801 standard
Diameters	3, 3.2/3.3, 3.5, 3.75, 4.2, 4.5, 5, 6	3, 3.5, 4.3, 5 – Fix Konisch™ 3.5, 3.75, 4.3, 5, 6 - Grand Konisch™	✓ Better. Medigma has wider variety of dimensions verified and

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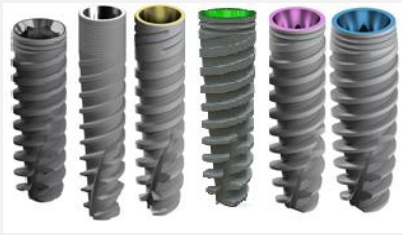
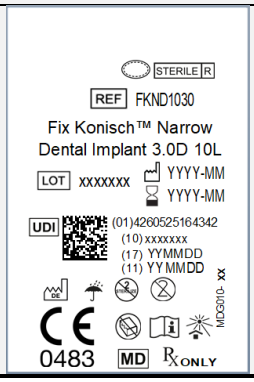
Product / Feature	Similar Device #2 – I5 Conical Implant by A.B. Dental	Medigma's Fix Konisch™ (ND, SD and WD) and Grand Konisch™ dental implants	Medigma's Dental Implants approach [=, ✓, ✖]
			validated by pre-clinical testing.
Lengths	10, 11.5, 13, 16 (for 3-3.5mmD), 8, 10, 11.5, 13, 16 (for 3.75 and 4.2mmD) 6, 8, 10, 11.5, 13, 16 (for 4.5 – 6mmD)	Fix Konisch™: 10, 11.5, 13, 16, 18 (for 3.0mmD). 8, 10, 11.5, 13, 15, 18 (for 3.4, 4.3 and 5.0mmD). Grand Konisch™: 8, 10, 11.5, 13, 16, 18 (for 3.5mmD). 8, 10, 11.5, 13, 16, 18, 20, 22.5, 25 (for 3.75mmD) 6.0, 8, 10, 11.5, 13, 16, 18, 20, 22.5, 25 (for 4.3 and 5.0mmD). 6.0, 8, 10, 11.5, 13 (for 6.0mmD).	= Same
Sterility	Sterile using gamma radiation	Sterile using gamma radiation	= Same
Prosthetic components	Healing abutments Cement-retained abutments (straight and angulated: 15°, 25°, 35°, 45°) Composed abutments – Plastic Sleeve with metal base (titanium, cobalt chrome or gold) Screw-retained abutments (straight and angular: 17°, 30°) Overdenture restorations (straight and angular) Lab products (CAD/CAM bases, individual block for milling)	Healing abutments. Cement-retained abutments (straight and angulated: 15°, 25°, 35° for IH and Grand Konisch platforms, 15°, 25° for ND platform, 15° for SD and WD platforms) UCLA Abutments – plastic casting sleeve and metal base (titanium, gold or cobalt chrome). Screw-retained abutments (straight and angulated: 17°, 30°, 45° for IH and Grand Konisch, 17°, 30° for ND, SD and WD) Overdenture restorations (straight). CAD/CAM components (Ti Bases, Ti Pre-Milled Abutment Blanks).	= Same
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design
Label			= Same

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Product / Feature	Similar Device #3 – Tapered Screw-Vent Implant by Zimmer Biomet	Medigma's Fix-a-Dent™ Dental Implants	Medigma's Dental Implants approach [=, ✓, ✗]
Intended use	Tapered Screw-Vent Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.	Medigma's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)	= Same
Surface treatment	Surface grit-blasting by hydroxylapatite followed by washing in acid to remove residual blasting material	AB/AE (Alumina Oxide blasted / Acid Etched	= Same
Basic design	Spiral, slightly tapered 1° to 4° degree of taper, triple-lead thread	Spiral, straight-walled and slightly tapered, double-lead thread	= Same
Implant-abutment connection	Internal hex	Internal hex	= Same
Diameters	3.7, 4.1, 4.7, 6.0	3.3, 3.75, 4.2, 5.0, 6.0	✓ Better. Medigma has wider variety of dimensions verified and validated by pre-clinical testing.
Lengths	10, 11.5, 13, 16	3.3mmD - 10, 11.5, 13, 16, 18 3.75mmD - 8, 10, 11.5, 13, 16, 18 4.2mmD - 6.25, 8, 10, 11.5, 13, 16, 18 5.0mmD - 6.25, 8, 10, 11.5, 13, 16 6.0mmD - 6.25, 8, 10, 11.5, 13	= Same
Sterility	Sterile using gamma radiation	Sterile using gamma radiation	= Same
Prosthetic components	Healing abutments Cement-retained abutments (straight and angulated: 17°, 20°) Screw-retained abutments (straight and angular: 15°, 30°) Overdenture restorations (straight)	Healing abutments Cement-retained abutments (straight and angulated: 15°, 25°, 35°) Screw-retained abutments (straight and angulated: 17°, 30°, 45°) Overdenture restorations (straight) CAD/CAM components (Ti Bases, Ti Pre-Milled Abutment Blanks)	✓ Better. Medigma has wider variety of dimensions verified and validated by pre-clinical testing.
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design

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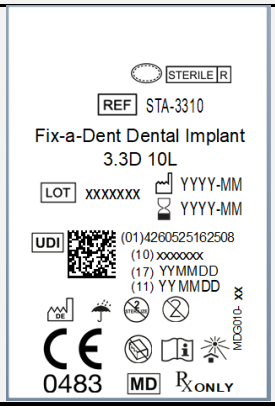
Product / Feature	Similar Device #3 – Tapered Screw-Vent Implant by Zimmer Biomet	Medigma's Fix-a-Dent™ Dental Implants	Medigma's Dental Implants approach [=, ✓, ✖]
Label			= Same

Product / Feature	Similar Device #4 – EH MONO Implant by ETGAR Medical Implant Systems	Medigma's Fix-1™ One-Piece Dental Implants	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	The EH MONO one-piece implant and abutment is specially tailored for narrow alveolar ridges and is ideal for maxillary lateral and mandibular incisors.	Medigma's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. Narrow implants identified as Fix-1™ One-piece dental implant in diameter of 3.0mm are indicated for use only in replacement of maxillary lateral incisors and mandibular lateral and central incisors.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	= Same
Surface treatment	sandblasting followed by acid etching surface treatment	AB/AE (Alumina Oxide blasted/Acid Etched	= Same
Basic design	Integrated abutment post. Threaded with double-lead thread	Integrated abutment post. Threaded with double-lead thread	= Same
Implant-abutment connection	N/A (Monoblock implant)	N/A (Monoblock implant)	= Same
Diameters	2.8, 3.3, 3.6, 4.2	3.0, 3.3, 3.6, 4.2, 5.0	✓ Better. Medigma has wider variety of dimensions verified and validated by pre-clinical testing.
Lengths	10, 11.5, 13, 15	10, 11.5, 13, 15	= Same
Sterility	Sterile using gamma radiation	Sterile using gamma radiation	= Same
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design

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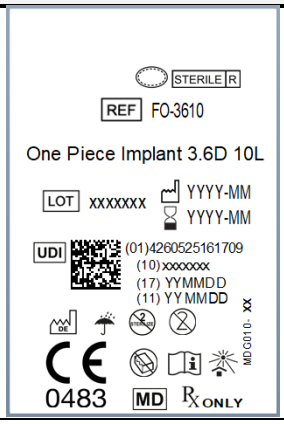
Product / Feature	Similar Device #4 – EH MONO Implant by ETGAR Medical Implant Systems	Medigma's Fix-1™ One-Piece Dental Implants	Medigma's Dental Implants approach [=, ✓, ✖]
Label			= Same

Product / Feature	Similar Device #5 – PteryFit by Norris Medical	Long Fix Konisch™ WD and Grand Konisch™ Implants	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	Norris Dental Devices' implants are intended for surgical placement in the posterior region of the atrophic Maxilla and located in the Pterygomaxillary region to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.	Medigma's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.	= Same. All products have the same intended use, Medigma has more restricted indication for narrow implants.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)	= Same
Surface treatment	RBM treatment to roughen the implant surface blasting with Hydroxyapetite for surface roughening and enhanced osseointegration.	Calcium Phosphate blasting	= Same
Basic design	Spiral, tapered with double threads. designed to match the anatomy of the bone structure- the implant is composed of 3 parts; The lower V-shaped thread zone enables self-tapping. The middle zone square type thread is used for compressing cancellous bone and help achieving maximum BIC. The smooth "Neck" surface at the top helps in eliminating the adherence of Perio-Pathogens, thus reducing the chances of an inflammatory process to develop around the neck area.	Spiral, tapered, double-lead thread. Smooth 'neck-collar' is 5 mm smooth in either bone level or up to 5mm above bone level.	= Same
Implant-abutment connection	Internal hex connection	Conical hex in Fix Konisch™ WD implants, Conical star in Grand Konisch™ implants.	= Same. Implant-abutment connection is verified and validated with fatigue test per ISO 14801:2016 standard
Diameters	4.2mm	4.3 mm – Fix Konisch™ 4.3 mm – Grand Konisch™	= Same
Lengths	20, 22, 25mm (for 4.2 diameters)	Fix Konisch™: 20, 22.5, 25mm (for 4.3mmD) Grand Konisch™: 20, 22.5, 25mm (for 4.3mmD)	= Same

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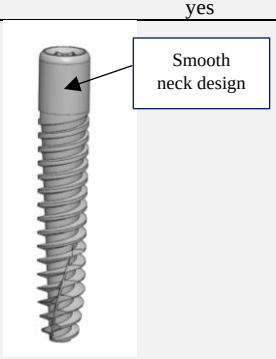
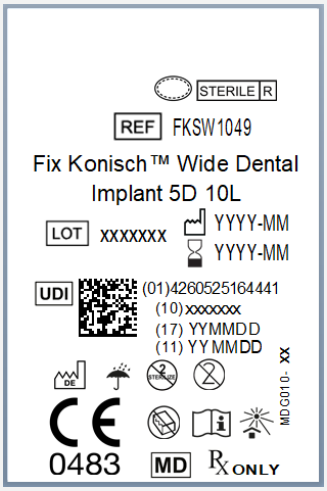
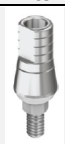
Feature \ Product	Similar Device #5 – PteryFit by Norris Medical	Long Fix Konisch™ WD and Grand Konisch™ Implants	Medigma's Dental Implants approach [=, ✓, ✖]
Sterility	Sterile using gamma radiation	Sterile using gamma radiation	= Same.
CE-Marked	Yes	yes	= Same
Illustrations		 Fix Konisch™ WD (long)	= Similar design
Label			= Same

Feature \ Product	Similar Device #6 –Straight Abutment by MIS Implants Technologies	Medigma's IH Straight Titanium Abutment	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	Dental abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacement to restore chewing function.	Dental abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacement to restore chewing function.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	= Same
Basic design	Cylindric shaped with conical hex connection	Cylindric shaped with conical hex connection	= Same
Diameters	Ø 4-5.5	Ø 1-5	
Lengths	10	10.5-14.30	= Same
Sterility	Non-Sterile. Cleaning and sterilization as recommended in the IFU	Non-Sterile. Cleaning and sterilization as recommended in the IFU	= Same.
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design

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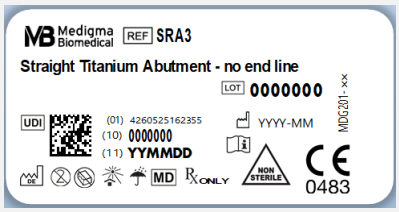
Feature \ Product	Similar Device #6 –Straight Abutment by MIS Implants Technologies	Medigma's IH Straight Titanium Abutment	Medigma's Dental Implants approach [=, ✓, ✗]
Label			= Same

Feature \ Product	Similar Device #7 – Multi Unit Abutment Xeal by Nobel BioCare	Medigma's Trans Mucosal Abutment	Medigma's Dental Implants approach [=, ✓, ✗]
Intended use	Multi-Unit abutment in combination with endosseous implants are indicated for multiple unit reconstruction when screw retained prosthetics is preferred.	Medigma's dental abutments are intended for use in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation, to support single and multiple tooth prosthesis in the mandible or maxilla.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)	= Same
Basic design	Have external Hex design at one side to engage with corresponding dental implant, and a cone design at the other side for engaging with temporary abutments or restorations. Have variation in cone angle to compensate different implant insertion directions.	Have external Hex design at one side to engage with corresponding dental implant, and a cone design at the other side for engaging with temporary abutments or restorations. Have variation in cone angle to compensate different implant insertion directions.	= Same
Angles	Straight, 17°, 30°	Straight, 17°, 30°, 45°	✓ Better. Medigma has wider variety of dimensions verified and validated by pre-clinical testing.
Lengths	Straight: 1.5, 4.5 mmL 17°: 2.5, 3.5 mmL 30°: 3.5, 5 mmL	Straight: 1, 2, 3, 4, 5 mmL 17°: 3, 4 mmL 30°: 3.5, 5 mmL	= Same. Medigma's length range is within the range that Nobel has to offer
Sterility	provided non-sterile and must be cleaned and sterilized prior to use, according to cleaning and sterilization instruction in the IFU.	provided non-sterile and must be cleaned and sterilized prior to use, according to cleaning and sterilization instruction in the IFU.	= Same
CE-Marked	Yes	Yes	= Same
Illustrations	 Angled Straight	 Angled Straight	= Similar design

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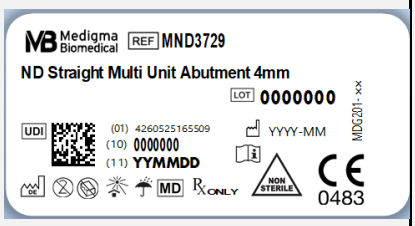
Product / Feature	Similar Device #7 – Multi Unit Abutment Xeal by Nobel BioCare	Medigma's Trans Mucosal Abutment	Medigma's Dental Implants approach [=, ✓, ✖]
Label			= Same

Product / Feature	Similar Device #9 – Titanium Base 2nd Generation by Medentika®	Medigma's Fix Konisch™ Ti Base Engaged	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	For the production of individual titanium/ceramic abutments (Hybrid abutments) on implants. Titanium/ceramic abutments consist of a titanium support the so-called titanium base 2nd Generation and a unique zirconia abutment. The individual titanium/ceramic abutments in combination with crowns and superstructures, for reconstruction of function and aesthetics be made.	Titanium base is intended for fabricating custom CAD/CAM abutments for single and multi-unit prostheses. (Abutment or directly bolted crown).	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)	= Same
Basic design	Have external Hex design or cylindrical shape at one side, for anti-rotation or free rotation, respectively. At the other side is cylindrical shaped for engaging with the final restoration. Fixed to corresponding implant through a prosthetic screw	Have external Hex design or cylindrical shape at one side, for anti-rotation or free rotation, respectively. At the other side is cylindrical shaped for engaging with the final restoration. Fixed to corresponding implant through a prosthetic screw	= Same
Diameters	Ø3.5, Ø4.5, Ø5.7	Ø3.0, Ø3.5, Ø4.3, Ø5	
Sterility	Titanium Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU	Titanium Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU	= Same
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design

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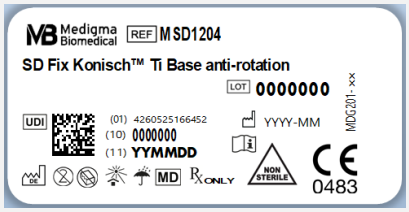
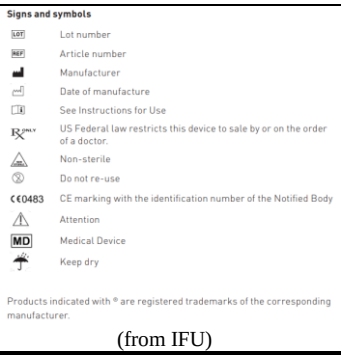
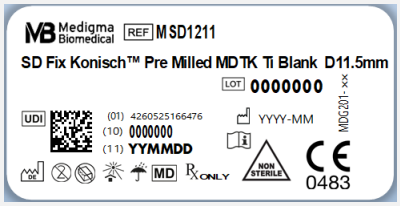
Product / Feature	Similar Device #9 – Titanium Base 2nd Generation by Medentika®	Medigma's Fix Konisch™ Ti Base Engaged	Medigma's Dental Implants approach [=, ✓, ✗]
Label			= Same

Product / Feature	Similar Device #10 – Pre-face Abutment Blank by Medentika®	Medigma's Fix Konisch™ Ti Pre Milled MDTK Abutment Blank	Medigma's Dental Implants approach [=, ✓, ✗]
Intended use	For the production of individual titanium/CoCr abutments on implants (using CAD/CAM milling machines). The individual titanium/CoCr abutments can be produced in combination with crowns and bridges for the restoration of function and esthetics.	Medigma CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple unit prostheses in the maxilla or mandible of a partially or fully edentulous patient.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patient	Partially or fully edentulous patient	= Same
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	= Same
Basic design	Titanium cylindrical shape with external Hex connection at on side to fit different implant platform. The cylinder/post intended to be milled to create customized abutment.	Titanium cylindrical shape with external Hex connection at on side to fit different implant platform. The cylinder/post intended to be milled to create customized abutment.	= Same
Diameters	Ø11.5, Ø16.0	Ø11.5, Ø15.8	
Sterility	The Ti Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU	The Ti Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU	= Same
CE-Marked	Yes	Yes	= Same
Illustrations			= Same
Label	 (from IFU)		= Same

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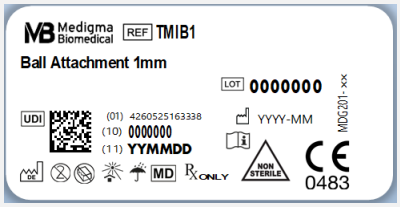
Product / Feature	Similar Device #11 –Ball Attachment by MIS Technologies	Medigma's Ball Attachment	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	The ball attachment superstructure is intended to secure a removable prosthesis.	The ball attachment superstructure is intended to secure a removable prosthesis.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy + Titanium nitride coating	Titanium alloy (Ti-6Al-4V ELI) + Anodize	= Similar
Basic design	Upper domain is ball shaped; lower domain connected to the implant has a threaded shape	Upper domain is ball shaped; lower domain connected to the implant has a threaded shape	= Same
Diameters	4-5mmD	2.59-5mmD	
Lengths	1, 2, 3, 4, 5	0.5, 1, 2, 3, 4	= Same
Sterility	Non-Sterile Cleaning and sterilization as recommended in the IFU	Non-Sterile Cleaning and sterilization as recommended in the IFU	= Same
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design
Label			= Same

Product / Feature	Similar Device #12 –Temporary Abutment by Nobel BioCare	Medigma's IH Temporary Abutment	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	= Same
Basic design	Cylindric shaped with internal hex connection	Cylindric shaped with internal hex connection. External features for cement retention	= Same
Diameters	Ø 4 – 5.5	Ø 2.30-4.5	
Lengths	12mm	11.5mm	= Same
Sterility	Non-Sterile Cleaning and sterilization as recommended in the IFU	Non-Sterile Cleaning and sterilization as recommended in the IFU	= Same.
CE-Marked	Yes	Yes	= Same

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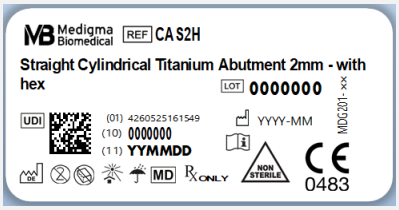
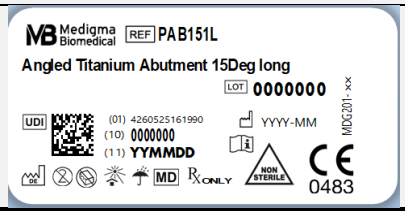
Feature \ Product	Similar Device #12 –Temporary Abutment by Nobel BioCare	Medigma's IH Temporary Abutment	Medigma's Dental Implants approach [=, ✓, ✖]
Illustrations			= Similar design
Label			= Same

Feature \ Product	Similar Device #13 – P4S-15 Anatomic angular abutment 15˚ with shoulder by AB Dental	Medigma's IH Angled Titanium Abutment	Medigma's Dental Implants approach [=, ✓, ✖]
Intended use	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.	= Same. All products have the same intended use
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients	= Same
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	= Same
Basic design	Cylindric 15˚ tilted shape	Cylindric 15˚ tilted shape	= Same
Diameters	Ø4	Ø4.7	
Lengths	1, 2, 3mm	1, 2, 3mm	= Same
Sterility	Non-Sterile Cleaning and sterilization as recommended in the IFU	Non-Sterile Cleaning and sterilization as recommended in the IFU	= Same.
CE-Marked	Yes	Yes	= Same
Illustrations			= Similar design
Label			= Same

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Appendix C - List of Applied Standards and Common Specifications

No.	Standard Source	Standard Number	Standard Name	Recent Revision	Level of compliance (fully or partially)
General					
1.	EN ISO	13485	Quality Systems – Medical Devices –System requirements for regulatory purposes	2016+ A11:2021	Fully, except for service provision and customer property (not applicable for Medigma's QMS).
2.	EN ISO	14971	Medical devices – Application of risk management to medical device	2019+ A11:2021	Fully, per FMEA method.
3.	EN ISO	10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;	2020	Fully, except for non-applicable tests based on device category and risk management process.
4.	EN	62366-1	Medical devices - Application of usability engineering to medical devices	2015+ A1:2020	Fully
5.	EN ISO	20417	Medical devices — Information to be supplied by the manufacturer	2021	Fully
6.	EN ISO	15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	2021	Fully
7.	ISO	14801	Dentistry – Implants – Dynamic fatigue test for endosseous dental implants	2016	Fully
Materials					
8.	ASTM	F136-13	Standard specification for wrought Titanium-6 Aluminium-4 Vanadium ELI (extra low interstitial) alloy for surgical implant applications	2021	Fully
9.	EN ISO	5832-3	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	2021	Fully
10.	ASTM	F1537-20	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	2020	Fully
11.	ISO	5832-12	Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium-molybdenum alloy	2019	Fully
Sterile Devices					
12.	EN	556-1	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2001	Fully
13.	EN ISO	11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2015+ A2:2019	Fully
14.	EN ISO	11137-2	Sterilization of health care products- radiation – Part 2: Establishing the sterilization dose	2015	Fully, in conjunction with ISO/TS 13004:2013
15.	EN ISO	11137-3	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control	2017	Fully
16.	ISO/TS	13004	Sterilization of health care products –Radiation – Substantiation of selected sterilization dose: Method VDmaxSD	2013	Fully in conjunction with EN ISO 11137-2:2015

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No.	Standard Source	Standard Number	Standard Name	Recent Revision	Level of compliance (fully or partially)
17.	EN ISO	11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020	Fully, per applicable selected tests for rigid microbial barrier package (tube).
18.	EN ISO	11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020	Full compliance with selected tests.
19.	EN ISO	11737-1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	2018+ A1:2021	Fully
20.	EN ISO	11737-2	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2020	Fully
Non-sterile devices					
21.	EN ISO	17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	2006	Fully
22.	ISO/TS	17665-2	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1	2009	Fully
Manufacture / processes					
23.	EN ISO	14644-1	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	2015	Fully. For ISO class 7
24.	EN ISO	14644-2	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015	Fully
25.	EN ISO	14644-3	Cleanrooms and associated controlled environments – Part 3: Test methods	2019	Fully
26.	EN ISO	14644-4	Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up	2001	Fully
27.	EN ISO	14644-5	Cleanrooms and associated controlled environments – Part 5: Operations	2004	Fully
28.	ISO	2859-1	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	1999 (A1:2011)	Fully

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