7/15/22

Biotech Dental, SAS
℅ Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K213997
Trade/Device Name: Kontact Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 9, 2022
Received: June 13, 2022

Dear Chris Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213997

Device Name

Kontact™ Dental Implant System

Indications for Use *(Describe)*

Kontact™ Dental Implant System is indicated for use in partially or fully edentulous patients to support maxillary or mandibular single unit, multiple-unit, or overdenture dental restorations. Kontact™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate. Kontact™ Dental Implant System 3 mm diameter implants and prosthetics components are indicated for use in surgical and restorative applications in the maxillary lateral incisor or mandibular incisor regions.

All digitally designed Kontact™ Dental Implant System CAD/CAM abutments are intended to be sent to a Biotech Dental validated milling center for manufacture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
K213997
Biotech Dental
Kontact™ Dental Implant System
7/15/2022

ADMINISTRATIVE INFORMATION

Manufacturer Name: Biotech Dental, SAS
305, Allées de Craponne
13300 Salon de Provence
Telephone: +33 04 90 44 60 60
Fax: +33 04 90 44 60 61

Official Contact: Delphine Mercier, VP Compliance
Email: d.mercier@biotech-dental.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Kontact™ Dental Implant System
Common Name:	Implant, Dental, Endosseous, Root-Form
Classification Name:	Endosseous dental implant
Classification Regulation:	21 CFR 872.3640
Device Class:	Class II
Product Code:	DZE, NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are the same or highly similar in indications, intended use and design principles to the following Primary Predicate device:

510(k)	Primary Predicate Device Name	Company Name
K210220	Kontact™ Dental Implant System	Biotech Dental, SAS

510(k)	Reference Device Name	Company Name
K122300	3i T3 Dental Implant	BIOMET 3i
K121787	Tapered Internal Plus Implants	BioHorizons Implant Systems, Inc.
K150203	Medentika CAD/CAM Abutments	Medentika GmbH
K200817	URIS OMNI Narrow System & Prosthetic	TruAbutment Inc.

INDICATIONS FOR USE

Kontact™ Dental Implant System is indicated for use in partially or fully edentulous patients to support maxillary or mandibular single unit, multiple-unit, or overdenture dental restorations. Kontact™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate. Kontact™ Dental Implant System 3 mm diameter implants and prosthetics components are indicated for use in surgical and restorative applications in the maxillary lateral incisor or mandibular incisor regions.

All digitally designed Kontact™ Dental Implant System CAD/CAM abutments are intended to be sent to a Biotech Dental validated milling center for manufacture.

DEVICE DESCRIPTION

The purpose of this submission is to expand the marketing clearance for Kontact™ Dental Implant System which comprises endosseous root-form dental implants and prosthetic components for single-unit, multi-unit, and overdenture restorations to include two additional implant body designs, new Narrow Conical and Conical abutments, hand-milled FitPost abutments, inserts for the previously cleared UniPost abutments and CAD/CAM Titanium base and Titanium Blank, dental implant abutments.

The Kontact™ Dental Implant System Subject device include two implant designs: Kontact S, and Kontact S+. The Kontact S and compatible Kontact implants are provided in five body diameters: 3.0 mm, 3.6 mm, 4.2 mm, 4.8 mm, and 5.4 mm. The body diameter for each implant is equal to the implant platform diameter. The 3.0 mm body implants have a smaller diameter and unique restorative interface. The 3.6 mm, 4.2 mm, 4.8 mm, and 5.4 mm implants share the same restorative interface. The Kontact and Kontact S implants are provided in lengths ranging from 8 mm to 16 mm.

The Kontact S+ implants are provided in four body diameters: 4.0 mm, 4.5 mm, 5.0 mm, and 5.5 mm. The 4.0 mm body diameter implants have an implant platform diameter of 3.6 mm. The 5.0 mm and 5.5 mm body diameter implants have an implant platform diameter of 4.2 mm. The 4.5 mm diameter implants are available in both 3.6 mm and 4.2 mm implant platform diameters. All Kontact S+ implants share the same restorative interface as the 3.6 mm and larger diameter Kontact and Kontact S implants. The Kontact S+ implants are provided in lengths ranging from 8 mm to 12 mm.

The implants have a recessed internal section for abutment indexing, and an internal threaded section for mating to the corresponding subject device cover screw, healing screw, or abutment screw. Kontact S and Kontact S+ implants are manufactured from Commercially Pure (CP) – Grade 4 titanium conforming to ASTM F67 and ISO 5832-2. The endosseous threaded surface of the Kontact S and Kontact S+ implants are grit-blasted with resorbable beta-tricalcium phosphate (β-TCP) particles.

Grit-blasting of the Kontact S and Kontact S+ implants create a roughened surface which provides an increase in total contact area of the implant surface to facilitate osseointegration.

Kontact™ Dental Implant System – Kontact S and Kontact S+ Implant Sizes

Implant Type	Implant Body Diameter (mm)	Implant Platform Diameter (mm)	Lengths (mm)
Kontact S	Ø 3.0	Ø 3.0	10, 12, 14
	Ø 3.6	Ø 3.6	8, 10, 12, 14, 16
	Ø 4.2	Ø 4.2	8, 10, 12, 14, 16
	Ø 4.8	Ø 4.8	8, 10, 12, 14
	Ø 5.4	Ø 5.4	8, 10, 12, 14
Kontact S+	Ø 4.0	Ø 3.6	8, 10, 12
	Ø 4.5	Ø 3.6	8, 10, 12
	Ø 4.5	Ø 4.2	8, 10, 12
	Ø 5.0	Ø 4.2	8, 10, 12
	Ø 5.5	Ø 4.2	8, 10, 12

The Subject device prosthetic components include seven implant abutment designs: Straight Conical, 30° Angulated Conical (indexed and non-indexed), Titanium Base, Titanium Blank and FitPost. The abutments designs are compatible with the Kontact, Kontact S and Kontact S+ implants. All Subject device abutments are manufactured titanium alloy conforming to ASTM F136 and ISO 5832-3. The Subject device prosthetic components are summarized in the following tables.

Kontact™ Dental Implant System – Prosthetic Components

Implant Diameter Kontact S (mm)	Implant Platform Diameter Kontact S (mm)	Prosthetic Interface (implant/ abutment) Diameter (mm)	Subject Device Abutment Designs for Kontact S Implants						
			Straight Narrow Conical Multi-Unit  (non-indexed)	30° Angulated Narrow Conical and Conical Multi-Unit  (indexed)	30° Angulated Conical Multi-Unit  (non-indexed)	Titanium Base (CAD/CAM) 	Titanium Blank (CAD/CAM) 	FitPost (Hand Milled) 	Screws* 
3.0	3.0	2.49	n/a	n/a	n/a	X	X	n/a	X
3.6	3.6	2.89	X	X	X	X	X	X	X
4.2	4.2	2.89	X	X	X	X	X	X	X
4.8	4.8	2.89	X	X	X	X	X	X	X
5.4	5.4	2.89	X	X	X	X	X	X	X
Material			Grade 5 – Titanium						
Finish			None	Blue Anodize	None	Yellow Anodize	None	None	None

Implant Diameter Kontact S+ (mm)	Implant Platform Diameter Kontact S+ (mm)	Prosthetic Interface (implant/ abutment) Diameter (mm)	Subject Device Abutment Designs for Kontact S+ Implants						
			Straight Narrow Conical Multi-Unit  (non-indexed)	30° Angulated Narrow Conical and Conical Multi-Unit  (indexed)	30° Angulated Conical Multi-Unit  (non-indexed)	Titanium Base (CAD/CAM) 	Titanium Blank (CAD/CAM) 	FitPost (Hand Milled) 	Screws* 
4.0, 4.5	3.6	2.89	X	X	X	X	X	X	X
4.5, 5.0, 5.5	4.2	2.89	X	X	X	X	X	X	X
Material			Grade 5 – Titanium						
Finish			None	Blue Anodize	None	Yellow Anodize	None	None	None

*3.0 mm Abutment screw – TiN-coated Phynox, not titanium

Implant Diameter Kontact (mm)	Implant Platform Diameter Kontact (mm)	Prosthetic Interface (implant/ abutment) Diameter (mm)	Subject Device Abutment Designs Compatible with Kontact Implants						
			Straight Narrow Conical Multi-Unit  (non-indexed)	30° Angulated Narrow Conical and Conical Multi-Unit  (indexed)	30° Angulated Conical Multi-Unit  (non-indexed)	Titanium Base (CAD/CAM) 	Titanium Blank (CAD/CAM) 	FitPost (Hand Milled) 	Screws* 
3.0	3.0	2.49	n/a	n/a	n/a	X	X	n/a	X
3.6	3.6	2.89	X	X	X	X	X	X	X
4.2	4.2	2.89	X	X	X	X	X	X	X
4.8	4.8	2.89	X	X	X	X	X	X	X
5.4	5.4	2.89	X	X	X	X	X	X	X
Material			Grade 5 – Titanium						
Finish			None	Blue Anodize	None	Yellow Anodize	None	None	None

EQUIVALENCE TO MARKETED DEVICE

The Subject device is the same or highly similar in indications and design principles to the Primary Predicate device listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and tables comparing the technological characteristics of the Subject device, the Primary Predicate device and Reference devices.

The wording of the Indications for Use Statement (IFUS) of the Subject device is highly similar to the to that of the K210220 Primary Predicate device, differing only in the inclusion of the full device name, in reference to the 3 mm implants and the final paragraph which has been added to the IFUS to support fabrication of customized endosseous dental implant abutments by means of CAD/CAM technology. Similarly, the differences between the Subject device IFUS and that of each of the Reference devices are related to the specific device names and design features, validated milling centers, and the compatible implant lines. None of these minor differences impact substantial equivalence because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

TECHNOLOGICAL CHARACTERISTICS

Subject device implants and abutments are the same or highly similar in intended use and designs to the sponsor's K210220 Primary Predicate device. The Subject device is to be sterilized by the end-user, using the same methods as previously validated for the sponsor's K210220 Primary Predicate device. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Reference devices introduce additional abutment designs with the same or highly similar intended uses.

Implants

The Subject device Kontact S implants have the same implant diameter, platform diameter and lengths as the sponsor's Kontact K210220 Kontact implants but differ in material and modified surface treatment. The K122300 Reference device has similar implant and prosthetic diameters and similar implant lengths and is made from the same raw material as the Subject device Kontact S and Kontact S+ implants. Reference device K121787 is grit-blasted with the manufacturer's Resorbable Blast Texture (RBT) media (tricalcium phosphate) in a similar manner to the Subject device Kontact S implants supporting this technology in the Subject device. Additionally, the K121787 Reference device has similar encompasses similar implant dimensions. Slight differences between Subject device implants and Primary Predicate and Reference device implant dimensions and modified surfaces do not change the intended use of the devices and have been mitigated through non-clinical performance testing to demonstrate the Subject device is sufficient for intended use.

Abutments

The Subject and Primary Predicate device abutments are for single-unit or multi-unit restorations, have internal implant interface connections, and are made of Ti-6Al-4V ELI alloy (abutments and abutment screws). The Subject device abutment designs are highly similar to that of the K210220 Primary Predicate device designs: Straight Conical, Conical, Angulated Narrow Conical, Angulated Conical abutments. Titanium base, Titanium Blank and FitPost abutments are added by Reference devices.

Straight Narrow Conical Abutments

The K200817 Reference device is included for support of dental implant abutments which include a larger prosthetic diameter and the same and larger gingival height of the previously cleared Straight Narrow Conical abutments.

Angulated Narrow Conical and Angulated Conical Abutments

The Primary Predicate devices were limited to 17° angle correction. The K200817 Reference device in included in this submission to support the use of dental implant abutments which include a larger post correction angle and

similar prosthetic diameter and gingival height. Angulated Narrow Conical and Angulated Conical Abutments and intended for multi-unit restorations.

Titanium Base Abutments

The Subject device Titanium base abutments are similar in design, materials, fabrication process and use as the K150203 Reference device. The Subject and K150203 Reference devices encompass a similar range of implant platforms. The Titanium Base Abutments consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment made of Zirconia conforming to ISO 13356) that composes the final abutment.

Titanium Blank Abutments

The Subject device Titanium base abutments are similar in design, materials, fabrication process and use as the K150203 Reference device. The Subject and K150203 Reference devices encompass a similar range of implant platform diameters, and both have a maximum post correction angle of 30 degrees (15 degrees for 3 mm implants).

FitPost Abutments

The Subject device FitPost abutments are similar in design, fabrication process and K210220 Primary Predicate device. They differ only in that they are provided with a pre-manufactured 30° post which can be customized for individual patient requirements. The K150203 Reference device is included to support the use of a modified abutment with a 30° post correction angle with similar implant platform diameters. While the methods of modification are different, both the Subject and Reference device are limited to 30° angulation. The compatible Kontact implant system is limited to 22° based on performance testing. The hand milling method of modification of an abutment is supported by the sponsor's K210220 Primary Predicate device.

Uni-Post Copings

Uni-Post Abutments were cleared as part of the K210220 Primary Predicate device and are cleared for use with Titanium sleeves which complete the two-part abutment upon the final prosthesis is cemented to. The Uni-Post copings in this submission perform the same function as the titanium sleeve but do so without the need to be hand modified for patient occlusion. The Uni-Post copings are similar to and supported by both the Uni-Post titanium sleeve and the titanium coping of the straight Conical Abutments of the K210220 Primary Predicate device. The Uni-Post copings share the same prosthetic diameters 4 mm, 5mm and 6.5 prosthetic diameters of the Primary Predicate device titanium sleeves and are similar to the 4.9 mm prosthetic diameter of the Conical Abutment copings.

Slight differences in dimensions between the Subject device copings and Primary Predicate device sleeves and copings are supported by the ISO 14801 performance testing of performed on worst-case constructs of the Subject device.

Minor differences in the designs, dimensions, or sizes between the Subject device, the Primary Predicate device, and the Reference devices do not affect substantial equivalence. Additional implant designs are supported by Reference devices. Overall, the Subject, Primary Predicate and Reference devices encompass a similar range of physical dimensions. Minor differences related to implant or abutment designs are mitigated by mechanical performance testing. ISO 14801 mechanical performance testing was performed on worst-case constructs of the Subject device to demonstrate suitability for intended use of the Subject device implant platform, gingival height, and post correction angles combinations.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: Biocompatibility evaluation and testing in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"; static compression and compression fatigue testing according to ISO 14801, Steam Sterilization Validation according to ISO 17665-1 and ISO TS 17665-2, and an MRI Safety assessment.

The following confirmatory biological tests were performed:

Biological Endpoint	**Relevant Standard**
Cytotoxicity	ISO 10993-5:2009
Endotoxins	ANSI/AAMI ST72:2019

The biological evaluation included review of published literature, internal routine monitoring data related to implant modified surface treatment and post-market surveillance data on implants subject to the same modified surface treatment and cleaning process and made from the same material as the Subject device according to the following FDA guidance documents, *Acceptance of Clinical Data to Support Medical Device Applications and Submissions* and *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*.

A published multi-center retrospective study evaluated implant failures and bone-level changes on male and female patients aged 19-90 years old implanted with the Subject device implants of varying diameters and lengths. Placement locations varied and included placement in extraction sockets, healed bone, and grafted bone locations. Bone levels of 326 were evaluated at time of abutment placement through a period of 50 months post implantation. Bone level decreases identified were less than 1 mm, well within accepted levels, with an overall implant survival rate of 98% at 1 year.

Review of historical SEM/EDS data was performed on implants made from the same material and surface treatment process as those covered in the published literature. Review of post market surveillance data and was performed to identify any significant trends in osseointegration failures. The results indicated failure rates below industry levels.

The endotoxin batch protocol and gamma sterilization validations were leveraged from the prior K210220 Primary Predicate device clearance.

Non-clinical worst-case MRI review was performed to evaluate the Subject device components in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Any differences in implant or implant abutment designs or dimensions have been mitigated and demonstrated to be suitable for intended use through non-clinical bench performance testing.

The results of non-clinical performance testing demonstrate that the Subject device is suitable for intended use and is the same or highly similar to the Primary Predicate device.

CLINICAL TESTING

No animal or clinical testing was performed for this Premarket Notification.

CONCLUSION

Overall, the Indications for Use statement for the Subject and Primary Predicate devices are the highly similar, differing slightly, only in device name. Overall, the Technological Characteristics of the Subject device are the same or highly similar to the Primary Predicate and Reference devices with any differences mitigated through non-clinical performance testing.

Overall, the data included in this premarket notification demonstrates substantial equivalence to the Primary Predicate device listed above.

Indications for Use Comparison Table

<table>
<tr>
<th>Subject Device
Kontact™ Dental Implant System Biotech Dental, SAS</th>
<th>Primary Predicate Device
Kontact™ Dental Implant System Biotech Dental, SAS
K210220</th>
<th>Reference Device
3i T3 Dental Implant BIOMET 3i
K122300</th>
<th>Reference Device
Tapered Internal Plus Implants BioHorizons Implant Systems, Inc.
K121787</th>
<th>Reference Device
Medentika CAD/CAM Abutments Medentika GmbH
K150203</th>
<th>Reference Device
Medentika CAD/CAM Abutments Medentika GmbH
K150203</th>
<th>Reference Device
URIS OMNI Narrow System & Prosthetic
TruAbutment Inc.
K200817</th>
</tr>
<tr>
<td>Kontact™ Dental Implant System is indicated for use in partially or fully edentulous patients to support maxillary or mandibular single unit, multiple-unit, or overdenture dental restorations. Kontact™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate. Kontact™ Dental Implant System 3 mm diameter implants and prosthetics components are indicated for use in surgical and restorative applications in the maxillary lateral incisor or mandibular incisor regions.

All digitally designed Kontact™ Dental Implant System CAD/CAM abutments are intended to be sent to a Biotech Dental validated milling center for manufacture.</td>
<td>Kontact™ Dental Implant System is indicated for use in partially or fully edentulous patients to support maxillary or mandibular single unit, multiple-unit, or overdenture dental restorations. Kontact Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate. Kontact 3 mm diameter implants and prosthetics components are indicated for use in surgical and restorative applications in the maxillary lateral incisor or mandibular incisor regions.</td>
<td>BIOMET dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdlentures.</td>
<td>BioHorizons Tapered Internal Plus Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.</td>
<td>Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.5, 4.3, 5.0</td><td>3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
<tr><td>Dentsply Friadent® Ankylos®</td><td>Y</td><td>3.5, 4.5, 5.5, 7.0</td><td>3.5, 4.5, 5.5, 7.0</td></tr>
</table>
Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td>
<td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
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<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>
Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td>
<td>URIS OMNI Narrow System is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, in support of single or multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

The URIS OMNI Prosthetic abutments are intended for use with URIS OMNI dental implants to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

All digitally designed abutments and/or coping for use with URIS OMNI Prosthetic abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.</td>
</tr>
</table>

Technological Characteristics Comparison Table – Implants

<table>
<tr><th>Comparison</th><th>Subject Device
Kontact™ Dental Implant System
Biotech Dental, SAS</th><th>Primary Predicate Device
Kontact™ Dental Implant System
Biotech Dental, SAS (K210220)</th><th>Reference Device
3i T3 Dental Implant
BIOMET 3i (K122300)</th><th>Reference Device
Tapered Internal Plus Implants
BioHorizons Implant Systems, Inc. (K121787)</th></tr>
<tr><td>Product Code</td><td>DZE, NHA</td><td>DZE, NHA</td><td>DZE</td><td>DZE</td></tr>
<tr><td>Regulation</td><td>872.3640, 872.3630</td><td>872.3640, 872.3630</td><td>872.3640</td><td>872.3640</td></tr>
<tr><td>Intended Use</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td></tr>
<tr><td>Reason for Predicate/Reference</td><td>Not Applicable</td><td>Implant diameter/length, prosthetic connection, sterilization, biocompatibility and how provided</td><td>Implant diameter/length, Implant material</td><td>β-TCP grit blast surface</td></tr>
<tr><td colspan="5">Implant Designs</td></tr>
<tr><td>Prosthetic Interface Connection</td><td>Internal</td><td>Internal</td><td>Internal</td><td>Internal</td></tr>
<tr><td>D = Implant Body Diameter
IP = Implant Platform Diameter</td><td>Kontact S
<table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>3.0</td><td>3.0</td><td>10, 12, 14</td></tr><tr><td>3.6</td><td>3.6</td><td>8,10,12,14,16</td></tr><tr><td>4.2</td><td>4.2</td><td>8,10,12,14,16</td></tr><tr><td>4.8</td><td>4.8</td><td>8,10,12,14</td></tr><tr><td>5.4</td><td>5.4</td><td>8,10,12,14</td></tr></table>Tapered Implant body, spherical apex
CP Grade 4 Titanium
β-TCP grit blast surface

Kontact S+
<table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>4.0</td><td>3.6</td><td>8, 10, 12</td></tr><tr><td>4.5</td><td>3.6</td><td>8, 10, 12</td></tr><tr><td>4.5</td><td>4.2</td><td>8, 10, 12</td></tr><tr><td>5.0</td><td>4.2</td><td>8, 10, 12</td></tr><tr><td>5.5</td><td>4.2</td><td>8, 10, 12</td></tr></table>Tapered Implant body, spherical apex
CP Grade 4 Titanium
β-TCP grit blast surface</td><td>Kontact
<table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>3.0</td><td>3.0</td><td>10, 12, 14</td></tr><tr><td>3.6</td><td>3.6</td><td>8,10,12,14,16</td></tr><tr><td>4.2</td><td>4.2</td><td>8,10,12,14,16</td></tr><tr><td>4.8</td><td>4.8</td><td>8,10,12,14</td></tr><tr><td>5.4</td><td>5.4</td><td>8,10,12,14</td></tr></table>Tapered Implant body, spherical apex
Grade 5 Titanium Alloy
AL_2O_3 grit blast surface</td><td>T3 Tapered Implants
<table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>4.0</td><td>3.4</td><td>8.5,10,11.5,13,15</td></tr><tr><td>5.0</td><td>4.1</td><td>8.5,10,11.5,13,15</td></tr><tr><td>6.0</td><td>5.0</td><td>8.5,10,11.5,13,15</td></tr></table>Tapered Implant body, spherical apex
CP Grade 4 Titanium
Discrete crystalline deposition (DCD), Calcium Phosphate (CaP) surface</td><td><table><tr><th>D</th><th>IP</th><th>Lengths</th></tr><tr><td>3.8</td><td>3.0</td><td>9,10.5,12,15</td></tr><tr><td>4.6</td><td>3.5</td><td>7.5,9,10.5,12,15</td></tr><tr><td>5.8</td><td>4.5</td><td>7.5,9,10.5,12,15</td></tr></table>Tapered Implant body, spherical apex
Grade 5 Titanium Alloy
β-TCP grit blast surface</td></tr>
<tr><td colspan="5">How Provided</td></tr>
<tr><td>Sterility</td><td>Gamma Sterilization</td><td>Sterile</td><td>Sterile</td><td>Sterile</td></tr>
<tr><td>Sterilization Method</td><td>Single patient, single use</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td></tr>
<tr><td>Usage</td><td></td><td>Single patient, single use</td><td>Single patient, single use</td><td>Single patient, single use</td></tr>
</table>

Technological Characteristics Comparison Table - Abutments

<table>
<tr><th>Comparison</th><th>Subject Device
Kontact™ Dental Implant System
Biotech Dental, SAS</th><th>Primary Predicate Device
Kontact™ Dental Implant System
Biotech Dental, SAS
K210220</th><th>Reference Device
Medentika CAD/CAM Abutments
Medentika GmbH
K150203</th><th>Reference Device
URIS OMNI Narrow System & Prosthetic
TruAbutment Inc.
K200817</th></tr>
<tr><td>Product Code</td><td>DZE, NHA</td><td>DZE, NHA</td><td>NHA</td><td>NHA</td></tr>
<tr><td>Regulation</td><td>872.3640, 872.3630</td><td>872.3640, 872.3630</td><td>872.3630</td><td>872.3630</td></tr>
<tr><td>Intended Use</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td></tr>
<tr><td>Reason for Predicate/Reference</td><td>Not Applicable</td><td>Abutment designs listed, material, sterilization, biocompatibility, how provided</td><td>CAD/CAM Ti-Base and Ti-Blank Abutment Design, Modified abutment maximum post correction angle</td><td>Straight MUA PD/GH, Angled Abutment increased post correction angle</td></tr>
<tr><td colspan="5">Abutment Design</td></tr>
<tr><td rowspan="3">D = Implant Body Diameter
IP = Implant Platform Diameter
GH = Gingival Height
PD = Prosthetic Diameter (Gingival Diameter)
CA = Post Correction Angle
PH = Post Height
APH = Accessory Post Height (Multi-Unit Abutments)</td>
<td>Straight Narrow Conical (non-indexed)
<table>
<tr><th>D</th><th>IP</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th><th>Min APH</th></tr>
<tr><td>3.6</td><td>3.6</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>4.2</td><td>4.2</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>4.8</td><td>4.8</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>5.4</td><td>5.4</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>4.0</td><td>3.6</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>4.5</td><td>3.6</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>4.5</td><td>4.2</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>5.0</td><td>4.2</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
<tr><td>5.5</td><td>4.2</td><td>5</td><td>4</td><td>0</td><td>1.2</td><td>3.2</td></tr>
</table>
Min PH with Conical coping 3.2 mm
Min PH with Titanium Sleeve 4 mm
Titanium Alloy (ASTM F136), no modified surface
Copings - anodized yellow</td>
<td rowspan="2">Narrow Conical Abutments
Implant Platform Diameter:
3.6, 4.2, 4.8, 5.4 mm
Prosthetic Platform Ø: 4.0 mm
Angle: 0°, Gingival Height: 1-4 mm
Angle: 17°, Gingival Height: 4 mm
Indexed, non-indexed
Titanium Alloy (ASTM F136)</td>
<td>n/a</td>
<td>Multi-Unit Straight Abutments
PD: 5.0mm
GH: 1.0/2.0/3.0/4.0/5.0/6.0 mm
PH: not defined</td></tr>
<tr><td>30° Angulated Narrow Conical (indexed)
<table>
<tr><th>D</th><th>IP</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th><th>Min APH</th></tr>
<tr><td>3.6</td><td>3.6</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>4.2</td><td>4.2</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>4.8</td><td>4.8</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>5.4</td><td>5.4</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>4.0</td><td>3.6</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>4.5</td><td>3.6</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>4.5</td><td>4.2</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>5.0</td><td>4.2</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
<tr><td>5.5</td><td>4.2</td><td>4</td><td>4</td><td>30</td><td>2.1</td><td>3.2</td></tr>
</table>
Min PH with Conical coping 3.2 mm
Min PH with Titanium Sleeve 4 mm
Titanium Alloy (ASTM F136), post insert - Anodized Blue
Copings - anodized yellow</td>
<td>n/a</td>
<td>Multi-Unit Angled Abutments
PD: 5.0mm
GH: 4.0/5.0/6.0mm
CA: 29.5
PH: not defined</td></tr>
<tr><td>30° Angulated Conical (indexed, non-indexed)
<table>
<tr><th>D</th><th>IP</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th><th>Min APH</th></tr>
<tr><td>3.6</td><td>3.6</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>4.2</td><td>4.2</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>4.8</td><td>4.8</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>5.4</td><td>5.4</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>4.0</td><td>3.6</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>4.5</td><td>3.6</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>4.5</td><td>4.2</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>5.0</td><td>4.2</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
<tr><td>5.5</td><td>4.2</td><td>2,3,4,5</td><td>4.9</td><td>30</td><td>2.3</td><td>4.0</td></tr>
</table>
Min PH with Conical coping 4.7 mm
Min PH with Titanium Sleeve 4 mm
Titanium Alloy (ASTM F136), no modified surface
Copings - anodized yellow</td>
<td>Angulated Conical Abutments
Implant Platform Diameter:
3.6, 4.2, 4.8, 5.4 mm
Prosthetic Platform Ø: 4.9 mm
Angle: 17°, Gingival Height: 2-5 mm
Indexed, non-indexed
Titanium Alloy (ASTM F136)</td>
<td>n/a</td>
<td>Multi-Unit Straight Abutments
PD: 5.0mm
GH: 4.0/5.0/6.0mm
CA: 29.5
PH: not defined</td></tr>
</table>

<table>
<tr><th>Comparison</th><th>Subject Device
Kontact™ Dental Implant System
Biotech Dental, SAS</th><th>Primary Predicate Device
Kontact™ Dental Implant System
Biotech Dental, SAS
K210220</th><th>Reference Device
Medentika CAD/CAM Abutments
Medentika GmbH
K150203</th><th>Reference Device
URIS OMNI Narrow System & Prosthetic
TruAbutment Inc.
K200817</th></tr>
<tr><td></td><td>Titanium Base
<table><tr><th>IP</th><th>GH</th><th>Max GH</th><th>PD</th><th>Max CA</th><th>PH</th></tr><tr><td>3.0</td><td>1.5, 3, 4, 5</td><td>5</td><td>3.9-6.4</td><td>0</td><td>4
5.5</td></tr><tr><td>3.6
4.2
4.8
5.4</td><td>0.7, 1, 2, 3, 4, 5</td><td>5</td><td>3.9-6.4</td><td>0</td><td>4.0
5.5</td></tr></table>Indexed, Titanium Alloy (ASTM F136)
Zirconia mesostructure conforming to ISO 13356
Anodized Yellow</td><td>n/a</td><td>Titanium Base:
Implant Platform Ø: 3.0-7.0 mm
Gingival Height: not specified
Angle: 0 - 30°
Min PH: not specified
Indexed, Non-indexed
Titanium Alloy</td><td>n/a</td></tr>
<tr><td></td><td>Titanium Blank
<table><tr><th>IP</th><th>Max GH</th><th>Max CA</th><th>Min PH</th></tr><tr><td>3.0</td><td>5</td><td>15</td><td>4</td></tr><tr><td>3.6</td><td>5</td><td>30*</td><td>4</td></tr><tr><td>4.2</td><td>5</td><td>30*</td><td>4</td></tr><tr><td>4.8</td><td>5</td><td>30*</td><td>4</td></tr><tr><td>5.4</td><td>5</td><td>30*</td><td>4</td></tr></table>Indexed
Titanium Alloy (ASTM F136), no modified surface
*Max 22° with Kontact Implants</td><td>n/a</td><td>Titanium Blanks:
Implant Platform Ø: 3.0-7.0 mm
Gingival Height: not specified
Angle: 0 - 30°
Min PH: not specified
Indexed
Titanium Alloy</td><td>n/a</td></tr>
<tr><td></td><td>FitPost (Hand Milled)
<table><tr><th>IP</th><th>GH</th><th>PD</th><th>Max CA</th><th>Min PH</th></tr><tr><td>3.6, 4.2, 4.8, 5.4</td><td>1, 2, 3, 4, 5</td><td>5</td><td>30*</td><td>4</td></tr></table>Indexed
Titanium Alloy (ASTM F136), no modified surface
*Max 22° with Kontact Implants</td><td>FitPost
Implant Platform Ø: 3.6, 4.2, 4.8, 5.4 mm
Prosthetic Diameter: 5.1, 6.6 mm
Gingival Height: 1-5 mm
Angle: 0°
Min PH: 4 mm
Indexed
Titanium Alloy (ASTM F136), no modified surface</td><td>Titanium Blanks:
Implant Platform Ø: 3.0-7.0 mm
Gingival Height: not specified
Angle: 0 - 30°
Min PH: not specified
Indexed
Titanium Alloy</td><td>n/a</td></tr>
<tr><td></td><td>Uni-Post Copings (for use with Uni-Post abutments)
(table reflects Uni-Post abutment with Insert)
<table><tr><th>IP</th><th>GH</th><th>PD</th><th>Max CA</th><th>PH</th><th>APH</th></tr><tr><td>3.6, 4.2, 4.8, 5.4</td><td>1, 2, 3, 4, 5</td><td>4, 5</td><td>0</td><td>2.1</td><td>4.9</td></tr><tr><td>3.6, 4.2, 4.8, 5.4</td><td>2, 3, 4, 5</td><td>6.5</td><td>0</td><td>2.1</td><td>4.9</td></tr></table>PH with Uni-Post Insert 4.9 mm
Titanium Alloy (ASTM F136), anodized yellow</td><td>Uni-Post Abutments w/Sleeves
Implant Platform Ø: 3.6, 4.2, 4.8, 5.4 mm
Prosthetic Diameter: 4, 5, 6.5 mm
Gingival Height: 1 mm – 5 mm

Straight Conical Abutment w/coping
Prosthetic Platform Ø: 4.0 mm, 4.9 mm
Gingival Height: 1-5 mm
Angle: 0°
Indexed, Non-Indexed
Grade 5 Titanium Alloy</td><td>n/a</td><td>n/a</td></tr>
<tr><td>Material
(Abutment and Screw)</td><td>Ti-6AL-4V Alloy
3.0 mm Abutment screw - Phynox</td><td>Ti-6AL-4V Alloy
3.0 mm Abutment screw - Phynox</td><td>Ti-6AL-4V Alloy</td><td>Ti-6AL-4V Alloy</td></tr>
<tr><td>Abutment/Implant Interface</td><td>Internal Connection</td><td>Internal Connection</td><td>Internal Connection</td><td>Internal Connection</td></tr>
<tr><td>Prosthesis Attachment</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td><td>Cement-retained</td><td>Multi-unit</td></tr>
<tr><td>Restoration</td><td>Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td><td>Multi-unit</td></tr>
<tr><td colspan="5">How Provided</td></tr>
<tr><td>Sterility</td><td>Non-Sterile</td><td>Non-Sterile</td><td>Non-Sterile</td><td>Non-Sterile</td></tr>
<tr><td>Sterilization Method</td><td>Moist Heat</td><td>Moist Heat</td><td>Moist Heat</td><td>Moist Heat</td></tr>
<tr><td>Usage</td><td>Single patient, single use</td><td>Single patient, single use</td><td>Single patient, single use</td><td>Single patient, single use</td></tr>
</table>