June 18, 2021

Biotech Dental, SAS
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K210220
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: May 17, 2021
Received: May 18, 2021

Dear Kevin Thomas:

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,

Andrew I. 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)*

K210220

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 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.

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.

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510(k) Summary
K210220
Kontact™ Dental Implant System
Biotech Dental, SAS

June 17, 2021

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Kontact™ Dental Implant System
Common Name	Implant, Endosseous, Root-Form Abutment, Implant, Dental, Endosseous
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary Product Code	NHA
Classification Panel:	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K120414, OsseoSpeed™ Plus, Astra Tech AB

Reference Devices
K123988, AnyOne™ Internal Implant System, MegaGen Implant Co., Ltd
K131644, Ankylos SynCone® Abutment 5°, Dentsply International, Incorporated
K153509, GPS® Angled Abutments, Implant Direct Sybron Manufacturing, LLC
K163194, Neodent Implant System - GM Line, JJGC Industria e Comercio de Materiais Dentarios SA
K170392, S.I.N. Dental Implant System, S.I.N. – Sistema de Implante Nacional S.A.
K182448, AnyRidge Octa 1 Implant System, MegaGen Implant Co., Ltd
K192347, ST Internal Implant System, MegaGen Implant Co., Ltd
K200992, S.I.N. Dental Implant System, S.I.N. – Sistema de Implante Nacional S.A.
K151328, PURE Ceramic Implants, Straumann, USA
K181381, A.B. Dental Devices® Dental Implants System, A.B. Dental Device Ltd.
K183518, Preat Abutments, Preat Corporation
K200386, Z5-BL, Z-Systems AG
K152787, ST Internal Fixture System, T-Plus Implant Tech. Co., Ltd.
K092341, Low Profile Abutment, Biomet 3i, Inc.
K203355, Straumann TLX Novaloc and Cementable Abutments, Institut Straumann AG

INDICATIONS FOR USE STATEMENT

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.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for Kontact™ Dental Implant System which comprises endosseous root-form dental implants, mating abutments, abutment screws, and other associated components for single-unit, multi-unit, and overdenture restorations.

Kontact dental implants are provided in five body diameters: 3.0 mm, 3.6 mm, 4.2 mm, 4.8 mm, and 5.4 mm. The platform diameter for each size is the same as the (maximum) body diameter. The implants are provided in lengths ranging from 8 mm to 16 mm. The subject device dental implants are summarized on the following page.

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. All implants are manufactured from titanium alloy conforming to ASTM F136 and ISO 5832-3. The endosseous threaded surface of the subject device implants is grit-blasted with non-resorbable aluminum oxide (Al_2O_3) particles. This rough surface provides an increase in total contact area of the implant surface to facilitate osseointegration.

Kontact™ Dental Implant Sizes

	Body Diameter (mm)	Lengths (mm)
Kontact Dental Implants	3.0	10, 12, 14
	3.6	8, 10, 12, 14, 16
	4.2	8, 10, 12, 14, 16
	4.8	8, 10, 12, 14
	5.4	8, 10, 12, 14

Kontact conventional and prosthetic components include cover screws, healing screws, abutment screws, temporary abutments, straight abutments, angled abutments, prepable abutments, multi-unit abutments, healing caps, and overdenture abutments. The Kontact abutment and prosthetic components are summarized in the following table.

Kontact™ Screws, Abutments, and Healing Caps

	Coronal Ø, mm	Angle, °	Material
Cover Screws	2.5 - 2.9	n/a	Titanium Alloy
Healing Screws	4.1 - 7.1	n/a	Titanium Alloy
Abutment Screws	2.0	n/a	Titanium Alloy, Cobalt Alloy
	Prosthetic Platform Ø, mm		
Temporary Abutments	4.0 - 4.5	n/a	Titanium Alloy
Non-Scalloped Straight Abutments	3.7 - 6.5	n/a	Titanium Alloy
Scalloped Straight Abutments	3.8 - 6.6	n/a	Titanium Alloy
Non-Scalloped Angled Abutments	3.7 - 6.5	7.5, 15, 22	Titanium Alloy
Scalloped Angled Abutments	3.8 - 6.6	7.5, 15, 22	Titanium Alloy
FitPost Abutment	5.1 - 6.6	n/a	Titanium Alloy
NanoPost Straight Abutments	4.3 - 5.5	n/a	Titanium Alloy
NanoPost Angled Abutments	4.3	7.5, 15	Titanium Alloy
NanoPost Healing Caps	4.3 - 5.5	n/a	PMMA
UniPost Abutments	4.0 - 6.5	n/a	Titanium Alloy
UniPost Healing Caps	4.0 – 6.5	n/a	PEEK
Straight Conical Abutments	4.0 - 4.9	n/a	Titanium Alloy
Angled Conical Abutments	4.0 - 4.9	17	Titanium Alloy
Conical Healing Caps	4.0 - 4.9	n/a	PEEK
IsoPost Straight Abutments	4.1	n/a	Titanium Alloy
IsoPost Angled Abutments	4.1	7.5, 15, 22	Titanium Alloy
IsoPost Healing Caps	4.9 -5.3	n/a	PEEK, PMMA
Ball Abutments	n/a	n/a	Titanium Alloy

Most device screws and all subject device abutments are manufactured from titanium alloy conforming to ASTM F136 and ISO 5832-3. Select subject device abutments and screws manufactured from titanium alloy are anodized using standard electrolytic passivation processing to impart a distinctive surface color. No dyes or color additives are used to impart color on the subject devices. All subject device screws and abutments corresponding to the subject device 3 mm diameter implants are anodized yellow. All other color-coded subject device components are anodized magenta, orange, green, blue, or brown.

The subject device abutment screw intended for 3 mm diameter implants and the prosthesis screw intended for conical abutments are manufactured from cobalt alloy, conforming to ASTM F1058 and ISO 5832-7. The abutment screw is coated with titanium nitride (TiN); the prosthesis screw is coated with chromium nitride (CrN). The coatings are created in a physical vapor deposition (PVD) process.

Subject device healing caps intended for use with UniPost abutments, conical abutments, and IsoPost abutments are manufactured from polyetheretherketone (PEEK). Subject device healing caps intended for NanoPost abutments and IsoPost abutments are manufactured from polymethyl methacrylate (PMMA).

PERFORMANCE DATA

The subject device was evaluated and tested as recommended in the FDA guidance documents *Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments* (issued May 12, 2004), *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (issued September 4, 2020), *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 17, 2015), *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 21, 2016), and *Pyrogen and Endotoxins Testing: Questions and Answer* (issued June 2012).

Non-clinical data submitted to demonstrate substantial equivalence included: gamma sterilization validation for subject device implants and cover screws according to ISO 11137-1 and ISO 11137-2; bacterial endotoxin (BET) testing including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 and USP 43-NF38:2020 <85>; shelf life validation through packaging stability per ASTM F1980 and in conformance with ISO 11607-1; moist heat sterilization (to be performed by the end-user) according to ISO 17665-1 and ISO TS 17665-2; biocompatibility according to ISO 10993-5 and ISO 10993-12; and static compression and compression fatigue testing according to ISO 14801.

The endosseous threaded surface of the subject device implants is grit-blasted with non-resorbable aluminum oxide (Al_2O_3) particles; this surface was validated by scanning electron microscope (SEM) and energy dispersive X-ray spectroscopy (EDS) characterization.

Bacterial endotoxins in the subject devices provided sterile to the end user will be monitored and controlled by measuring BET levels using a monthly sampling plan to ensure that the BET level meets the level of $\leq$ 20 EU/ device.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject devices are substantially equivalent in indications and design principles to the primary predicate device and reference devices 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 the reference devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate device K120414 and the reference devices. Slight differences in the language of the IFUS do not affect the intended use as an endosseous dental implant and dental implant abutments for support of a prosthesis to restore chewing function.

Minor differences between the IFUS for the subject device and the primary predicate device K120414 are listed below. These minor differences do not raise new questions of safety or effectiveness because the IFUS express equivalent intended use.

The predicate device IFUS states that the "The Astra Tech Dental Implants are intended for…immediate loading in all indications, except single tooth situations on implants shorter than 8 mm, or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may be appropriate." The subject device IFUS does not provide an exception for implant lengths shorter than 8 mm because the subject device implants range from 8 mm to 16 mm. Therefore, the exception is not applicable. The subject device IFUS states that "Kontact Dental Implant System is indicated for immediate loading when good primary stability is achieved and occlusal loading is appropriate." This statement is inclusive of soft bone (type IV).

Similarly, the subject device IFUS states more concisely, but inclusively, the primary predicate IFUS that "…Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective" with the sentence "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."

The predicate device IFUS states that "The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors." The subject device IFUS states that "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." The specification of "implants and prosthetic components" and "in surgical restorative applications" in the subject device IFUS is the same intended use compared to the more generic suggestion in the predicate device IFUS.

The predicate IFUS for the Atlantis Abutments is the same as the same intended use as the subject device IFUS for the Kontact Dental Implant System. The system includes both the subject device implants and the subject device prosthetic components.

The subject device does not include any patient-specific abutments or crowns fabricated using CAD-CAM technology; therefore, the subject device IFUS does not have an equivalent statement to the Atlantis™ Crown Abutment.

Minor differences between the IFUS for the subject device and the reference devices K123988, K182448, and K192347 are listed below. These minor differences do not raise new questions of safety or effectiveness because IFUS express equivalent intended use.

The reference device IFUS includes the terms “Crown, bridges, and overdentures” and the subject device IFUS uses alternative terminology “single-unit, multiple-unit, and overdenture dental restorations”.

The reference device IFUS states “Smaller implants (less than Ø 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading”. The subject device IFUS does not define implants with a diameter less than 6.0 mm as “smaller” or implants with a diameter 6.0 mm or greater as “larger” because the subject device implants are not provided in diameters greater than 5.4 mm. Therefore, the sentence “Kontact Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate” in the subject device IFUS is equivalent to the reference device’s “smaller implants” and a restriction on “larger” implants is not applicable

Conversely, the subject device IFUS includes a restriction on 3.0 mm diameter implants and the compatible prosthetic components to the maxillary lateral incisor and mandibular incisor regions. The reference device IFUS does not include the restriction because the smallest diameter reference device is 4.0 mm.

The reference device IFUS and the subject device IFUS include different tradenames.

Minor differences between the IFUS for the subject device and the reference device K131644 are listed below. These minor differences do not raise new questions of safety or effectiveness because the IFUS express equivalent intended use.

The reference device IFUS includes reference to edentulous mandible supported by 4 ANKYLOS® implants of at least 11 mm in length and placed interforaminally which is not applicable to the subject device IsoPost abutments.

The reference device IFUS and the subject device IFUS include different tradenames.

Minor differences between the IFUS for the subject device and the reference device K153509 are listed below. These minor differences do not raise new questions of safety or effectiveness because both IFUS express equivalent intended use.

The reference device IFUS and the subject device IFUS include different tradenames.

The reference device IFUS is limited to abutments for multi-unit bridge or overdenture that are compatible with original equipment manufacturer (OEM) implant systems. The subject device IFUS does not include compatible OEM implant systems because the subject devices and accessories are not compatible with any previously cleared dental implants or prosthetic components. Additionally, the subject device IFUS specifies the Kontact Dental Implant System, which encompasses implants, abutments, and accessories.

Minor differences between the IFUS for the subject device and the reference device K163194 are listed below. These minor differences do not raise new questions of safety or effectiveness because both IFUS express equivalent intended use.

The reference device IFUS includes indications for titanium base abutments and PEEK abutments. The subject device IFUS does not include these indications because the subject device product list does not include components that are indicated for use with CAD-CAM technology or abutments manufactured from PEEK. Subject device components manufactured from PEEK are limited to healing caps.

The reference device IFUS and the subject device IFUS include different tradenames.

Minor differences between the IFUS for the subject device and the reference device K170392 are listed below. These minor differences do not raise new questions of safety or effectiveness because both IFUS express equivalent intended use.

The reference device IFUS specifies that "Implants with lengths less than 7 mm are intended for delayed loading only." The subject device IFUS does not restrict implant lengths less than 7 mm for delayed loading only because the subject device implants range from 8 mm to 16 mm. Therefore, the restriction is not applicable.

The reference device IFUS and the subject device IFUS include different tradenames.

Minor differences between the IFUS for the subject device and the reference device K183518 are listed below. These minor differences do not raise new questions of safety or effectiveness because both IFUS express equivalent intended use.

The reference device IFUS and the subject device IFUS include different tradenames.

The reference device IFUS includes indications for titanium blanks and titanium base abutment, refences to validated milling centers, and compatible OEM implant systems. The subject device IFUS does not include these elements because the subject device does not include components that are indicated for use with CAD-CAM technology to fabricate patient-specific abutments prescribed by the clinician. Furthermore, the subject device and accessories are not compatible with any previously cleared dental implants or prosthetic components.

Minor differences between the IFUS for the subject device and the reference devices K152787, K092341, and K203355 include: only K152787 includes language regarding implants, and does not include any limitations for small diameter implants; K152787 and K092341 do not mention specific types of restorations (single-unit, multi-unit, or overdentures); and K203355 mentions only dentures. These minor differences do not raise new questions of safety or effectiveness because both IFUS express equivalent intended use.

Last, the differences in IFUS for K151328, K181381, and K200386 are not applicable for the assessment of substantial equivalence in terms of intended use because these are reference devices for materials and modified surface information.

Subject Device Dental Implants

The subject device Kontact dental implants are similar in designs and sizes to OsseoSpeed™ Plus implants cleared in the primary predicate K120414. The subject device implants are provided in body diameters of 3.0 mm, 3.6 mm, 4.2 mm, 4.8 mm, and 5.4 mm. The subject device implants are provided in total lengths ranging from 8 mm to 16 mm. The primary predicate device implants are provided in body diameters of 3.0 mm, 3.6 mm, 4.2 mm, 4.8 mm, and 5.4 mm and total lengths ranging from 6 mm to 17 mm. The platform diameter for each size is the same as the (maximum) body diameter for both the subject device and the primary predicate device. Both the subject device and primary predicate device implants have an anti-rotational feature for the implant-abutment interface. Both the subject device and primary predicate device are provided sterile to the end-user.

Additionally, the subject device Kontact dental implants are manufactured from titanium alloy conforming to ASTM F136 and ISO 5832-3. Titanium alloy is commonly used to manufacture dental implants and prosthetic components. The endosseous threaded surface of the subject device implants is grit-blasted with non-resorbable aluminum oxide (Al_2O_3) particles to facilitate osseointegration. The reference device K200386 is in support of substantial equivalence for this technological characteristic

because the endosseous threaded surface of the reference device also is modified by blasting with Al_2O_3 particles. Therefore, the subject device implants are substantially equivalent to the primary predicate K120414 and reference device K200386 implants.

Subject Device Prosthetic Components

The subject device Cover Screw and Ball Abutment designs are substantially equivalent in material and dimensions to similar devices in the primary predicate K120414.

The subject device Healing Screw designs are substantially equivalent in material and dimensions to similar healing abutments in reference devices in K123988 and K170392.

The subject device Temporary Abutment designs are substantially equivalent in material and dimensions to similar abutments in the reference devices K163194 and K192347. Similarly, the subject device UniPost Abutment designs are substantially equivalent in material and dimensions to similar abutments in the reference devices K163194, and to the EZ Post and Solid Abutments in K152787. The prosthetic post height of the UniPost Abutments is substantially equivalent to the Low Profile Abutment, K092341.

The subject device Non-Scalloped Straight Abutment and Scalloped Straight Abutment designs are substantially equivalent in material and dimensions to similar abutments in the reference devices K170392 and K192347.

The subject device Non-Scalloped Angled Abutment and Scalloped Angled Abutment designs are substantially equivalent in material and dimensions to similar abutments in the reference devices K123988, K182448, and K200992.

The subject device FitPost Abutments are substantially equivalent in intended use, material, and designs to the reference device Milling Abutment in K192347 and K182448, and to the Solid Abutments in K152787.

The subject device NanoPost Straight Abutments, NanoPost Angled Abutments, and Conical Abutments are substantially equivalent in material, design, and dimensions to similar abutments in the reference device K182448, and to the Low Profile Abutments, K092341.

The subject device IsoPost Abutments are substantially equivalent in material, design, and dimensions to the reference device K131644 and K153509, and to the Straumann TLX Novaloc Abutments in K203355.

Mechanical performance testing of the subject device was performed in conformance to ISO 14801. The reference device K183518 is to support substantial equivalence of the fatigue limit for subject device abutments compatible with the subject device 3.0 mm diameter implants. The fatigue limit data demonstrated that constructs of all other subject device abutments in combination with all other subject device implants have sufficient strength for their intended use.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate, and reference devices encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Comparison of Indications for Use Statements

	Indications for Use Statement
Subject Device	
Kontact Dental Implant System Biotech Dental, SAS	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.
Primary Predicate Device	
K120414 OsseoSpeed™ Plus Astra Tech AB	The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm, or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors. Abutments: Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Pius in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures. Atlantis Abutments: The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous; patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous; implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous; patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.
Reference Devices	
K123988 AnyOne™ Internal Implant System MegaGen Implant Co., Ltd	The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading
K131644 Ankylos SynCone® Abutment 5° Dentsply International, Incorporated	SynCone® Abutments on osseointegrate Implants Anchorage of dentures retained by taper friction and supported by ANKYLOS® implants. SynCone® Abutments for Immediate loading Immediate loading of an implant supported prosthesis in an edentulous mandible supported by 4 ANKYLOS® implants of at least 11 mm in length and placed interforaminally.
K153509 GPS® Angled Abutments Implant Direction Sybron Manufacturing LLC	GPS® Angled Abutments are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially or completely edentulous patient. These abutments are designed to only receive a fabricated multi-unit bridge or overdenture. Abutments are intended for use in the mandible or maxilla. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Compatibility: Legacy System: Prosthetically compatible with Zimmer Dental Tapered Screw-Vent system 3.5mm platform implants (3.7mmD, 4.1mmD, 8mm-16mm Length), 4.5mm platform implants (4.7mmD, 8mm-16mm Length), and 5.7mm platform implants (6.0mmD, 8mm-16mm Length). SwishTapered System: Prosthetically compatible with Straumann Standard and Standard Plus system RN platform implants (3.3mmD-4.8mmD, 6mm-16mm Length) SwishActive Implants: SwishActive implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) titanium abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform– 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5- 18mmLength). InterActive System: InterActive implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) titanium abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform– 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5- 18mmLength) implants.
K163194 Neodent Implant System - GM Line JJGC Industria e Comercio de Materiais Dentarios SA	Indications for Use for GM implants and conventional abutments: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Indications for Use for GM Titanium Base abutments: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. Indications for Use for GM Pro Peek Abutments: The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.
K170392 S.I.N. Dental Implant System S.I.N. - Sistema de Implante Nacional S.A.	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage approach is applied, the S.I.N Dental Implant System is intended for immediate loaded when good primary stability is achieved and with appropriate occlusal loading. Implants with lengths less than 7 mm are intended for delayed loading only.

Comparison of Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>K182448
AnyRidge Octa 1 Implant System
MegaGen Implant Co., Ltd</td><td>The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols:
- Delayed loading.
- Immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Larger implants are dedicated for the molar region.</td></tr>
<tr><td>K192347
ST Internal Implant System
MegaGen Implant Co., Ltd</td><td>The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 06.0mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.</td></tr>
<tr><td>K200992
S.I.N. Dental Implant System
S.I.N. - Sistema de Implante Nacional S.A.</td><td>S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage approach is applied, the S.I.N Dental Implant System is intended for immediate loaded when good primary stability is achieved and with appropriate occlusal loading.</td></tr>
<tr><td>Reference Devices</td><td></td></tr>
<tr><td>K151328
PURE Ceramic Implants
Straumann USA</td><td>The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components.
The Ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only.
The Straumann® PURE Ceramic Implant Protective Cap is intended to protect the Straumann® PURE Ceramic Implant (Monotype) during the healing phase after implant placement for up to 6 months.
Temporary copings are intended to serve as a base for temporary crown or bridge restoration for the Straumann® PURE Ceramic Implant (Monotype) for up to 30 days.</td></tr>
<tr><td>K181381
A.B. Dental Devices® Dental Implants System
A.B Dental Device Ltd</td><td>A.B. DENTAL DEVICES® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. A.B. DENTAL DEVICES® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</td></tr>
<tr><td>K183518
Preat Abutments,
Preat Corporation</td><td>Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment. All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>3i OSSEOTITE® Certain®</td><td>3.25</td><td>3.4</td></tr>
<tr><td></td><td>4.0</td><td>4.1</td></tr>
<tr><td></td><td>5.0</td><td>5.0</td></tr>
<tr><td></td><td>6.0</td><td>6.0</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>3.0</td><td>3.0</td></tr>
<tr><td></td><td>3.5, 4.0</td><td>3.5/4.0</td></tr>
<tr><td></td><td>4.5, 5.0</td><td>4.5/5.0</td></tr>
<tr><td>BioHorizons Tapered Internal</td><td>3.0</td><td>3.0</td></tr>
<tr><td></td><td>3.5</td><td>3.5</td></tr>
<tr><td></td><td>4.0</td><td>4.5</td></tr>
<tr><td>HIOSSEN ET III</td><td>3.5</td><td>Mini</td></tr>
<tr><td></td><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular</td></tr>
<tr><td>Implant Direct Legacy</td><td>3.2</td><td>3.0</td></tr>
<tr><td></td><td>3.7, 4.2</td><td>3.5</td></tr>
<tr><td></td><td>4.7, 5.2</td><td>4.5</td></tr>
<tr><td></td><td>5.7, 7.0</td><td>5.7</td></tr>
<tr><td>MegaGen AnyRidge</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>3.5</td></tr>
<tr><td>Neoss</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>4.1</td></tr>
<tr><td>NobelActive®</td><td>3.5</td><td>NP</td></tr>
<tr><td></td><td>4.3, 5.0</td><td>RP</td></tr>
<tr><td>Nobel Replace™</td><td>3.5</td><td>NP</td></tr>
<tr><td></td><td>4.0, 4.3, 5.0</td><td>RP</td></tr>
<tr><td></td><td>5.0</td><td>WP</td></tr>
<tr><td></td><td>6.0</td><td>6.0</td></tr>
<tr><td>Straumann® Bone Level</td><td>3.3</td><td>NC</td></tr>
<tr><td></td><td>4.1, 4.8</td><td>RC</td></tr>
<tr><td>Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN</td></tr>
<tr><td></td><td>4.8, 6.5</td><td>WN</td></tr>
<tr><td>Zimmer Screw-Vent®/Tapered Screw-Vent®</td><td>3.5, 3.7, 4.1</td><td>3.5</td></tr>
<tr><td></td><td>4.7</td><td>4.5</td></tr>
<tr><td></td><td>6.0</td><td>5.7</td></tr>
</table></td></tr>
<tr><td>K200386
Z5-BL
Z-Systems AG</td><td>Z5-BL implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5-BL implants are suitable for patients with metal allergies and the chronic diseases resulting from them. Z5-BL implants are intended for delayed loading.</td></tr>
<tr><td>K152787
ST Internal Fixture System
T-Plus Implant Tech. Co., Ltd.</td><td>The ST internal Fixture System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient’s chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
The ST Internal Fixture System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</td></tr>
<tr><td>K092341
Low Profile Abutment
Biomet 3i, Inc.</td><td>BIOMET 3i Low Profile Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device.in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained to the abutment.</td></tr>
<tr><td>K203355
Straumann TLX Novaloc and Cementable Abutments
Institut Straumann AG</td><td>TLX Novaloc Abutments
The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants (NT, RT, and WT).
TLX Cementable Abutments
Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Final abutments may be placed into occlusion for implants with sufficient primary stability and with appropriate occlusal loading to restore chewing function or for implants that are fully osseointegrated.</td></tr>
</table>

Comparison of Technological Characteristics, Implants

Feature	Subject Device	Primary Predicate	Reference Device
		K120414	K200386
	Kontact Dental Implant System	OsseoSpeed™ Plus	Z5-BL
	Biotech Dental, SAS	Astra Tech AB	Z-Systems AG
Product Code	DZE, NHA	DZE, NHA	DZE, NHA
Reason for Predicate/ Reference Device	n/a	Implant body/platform diameter, length, and how provided	Implant Endosseous Surface
Implant Designs			
Prosthetic Interface Connection	Internal	Internal	Internal
Body/Platform Diameter, mm	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8. 5.4	3.6
Lengths, mm	8, 10, 12, 14, 16	6, 8, 9, 11, 13, 15, 17	8, 10, 12
Implant Material	Titanium alloy (ASTM F136 and ISO 5832-3)	Commercially pure titanium (ASTM F67)	Y-TZP zirconia conforming to ISO 13356
Implant Endosseous Surface	Aluminum Oxide (Al_2O_3) Blasted	OsseoSpeed, TiO_2-blasted fluoride-modified	Aluminum Oxide (Al_2O_3) Blasted
How Provided			
Sterility	Sterile	Sterile	Sterile
Sterilization Method	Gamma Sterilization	Not publicly available	Plasma Gas
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use

Comparison of Technological Characteristics, Prosthetic Components

Feature	Subject Device	Primary Predicate Device	Reference Devices										
	K120414	K123988	K170392	K163194	K192347	K182448	K200992	K131644	K153509	K152787	K092341	K203355
	Kontact Dental Implant System	OsseoSpeed™ Plus	AnyRidge Octa 1 Implant System	S.I.N. Dental Implant System	Neodent Implant System - GM Line	ST Internal Implant System	AnyRidge Octa 1 Implant System	S.I.N. Dental Implant System	Ankylos SynCone® Abutment 5°	GPS® Angled Abutment	ST Internal Fixture System	Low Profile Abutment	Straumann TLX Novaloc and Cementable Abutments
	Biotech Dental, SAS	Astra Tech AB	MegaGen Implant Co., Ltd	S.I.N. - Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios SA	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd	S.I.N. - Sistema de Implante Nacional S.A.	Dentsply International, Incorporated	Implant Direct Sybron Manufacturing, LLC	T-Plus Implant Tech. Co., Ltd.	Biomet 3i, Inc.	Institut Straumann AG
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	NHA	NHA	DZE< NHA	NHA	NHA
Reason for Predicate/ Reference Device	n/a	Cover Screw Ball Abutments design and dimensions	Healing Screws Temporary Abutments design and dimensions	Healing Screws Straight Abutments design and dimensions	Temporary Abutments UniPost Abutments design and dimensions	Temporary Abutments Straight Abutments FitPost Abutment design and dimensions	Conical Abutments NanoPost Abutments FitPost Abutment Angled Abutments designs and dimensions	Angled Abutments designs and dimensions	IsoPost Abutments designs and dimensions	IsoPost Abutments designs and dimensions			
Abutment Designs													
Cover Screws	Coronal Ø: 2.5 mm, 2.9 mm Non-Indexed Titanium Alloy (ASTM F136), anodized and non-anodized	Coronal Ø: 2.5-4.6 mm Non-Indexed Titanium Alloy, anodized											
Healing Screws	Coronal: Ø 4.1-7.1 mm Gingival Height: 1-5 mm Non-Indexed Titanium Alloy (ASTM F136) anodized and non-anodized		Healing Abutment Coronal Ø 4.2-9.7 mm Gingival Height: 2.3-6.8 mm Non-Indexed Ti-6A1-4V ELI	Healing Abutment Unitite Coronal: Ø 3.3, 4.5 mm Gingival Height 0.8-5.5 mm Non-Indexed Titanium Alloy (ASTM F136)									
Temporary Abutments	Prosthetic Platform Ø: 4.0 mm, 4.5 mm Gingival Height: 1-5 mm Indexed Titanium Alloy (ASTM F136) Knurled				GM Exact Abutments Prosthetic Platform Ø: 3.5 mm, 4.8 mm GH: 0.8-5.5 mm Non-Indexed Ti-6A1-4V ELI (ASTM F136)	Temporary Abutment Prosthetic Platform Ø:4.0 mm, 4.5 mm Gingival Height: 1.0 mm, 3.0 mm Indexed & Non-Indexed Ti-6A1-4V ELI Grooved							
Straight Abutments	Prosthetic Platform Ø: 3.7-6.6 mm Gingival Height: 1-5 mm Angle: 0° Indexed and Non-Indexed Titanium Alloy (ASTM F136), anodized and non-anodized			Abutment Cemented SIT Unitite Prosthetic platform Ø 3.3 mm, 4.5 mm Gingival height: 0.8-5.5 mm Angle 0° Non-indexed Titanium Alloy (ASTM F136)		Solid Abutment Prosthetic Platform Ø: 4-7 mm Gingival Height: 1-5.0 mm Angle: 0° Indexed Ti-6A1-4V ELI, anodized							
Angled Abutments	Prosthetic Platform Ø: 3.7– 6.6 mm Gingival Height: 1-5 mm Angle: 7.5°, 15°, 22° Indexed, Non-Indexed Titanium Alloy (ASTM F136), anodized, non-anodized		Angled Abutment Prosthetic Platform Ø: 4.5 mm, 5.5 mm Gingival Height: 2.5 mm, 4.5 mm Angle: 15°, 25° Indexed and Non-Indexed Ti-6A1-4V ELI, anodized				Angled Abutment Prosthetic Platform Ø: 4-7 mm Gingival Height: 1-5 mm Angle: 15°, 25° Indexed & Non-Indexed Ti-6A1-4V ELI, anodized, non-anodized	Abutment Angled Morse Prosthetic Platform Ø: 3.5, 4.5 mm Gingival Height: 1-5 mm Angle: 17° Indexed Titanium Alloy (ASTM F136)					
FitPost Abutment	Prosthetic Platform Ø: 5.1 mm, 6.6 mm Gingival Height: 1-5 mm Angle: 0° Indexed Titanium Alloy (ASTM F136)					Milling Abutment Prosthetic Platform Ø: 4-7 mm Gingival Height: 1.5 mm, 3.0 mm Angle: 0° Indexed Ti-6A1-4V ELI, anodized	Milling Abutment Prosthetic Platform Ø: 6.0 mm, 8.0 mm Gingival Height: 1-5 mm Angle: 0° Indexed & Non-Indexed Ti-6A1-4V ELI, anodized				Solid Abutments Ø: 5.0-6.0 mm Gingival Height: 1 mm		
NanoPost Straight Abutments	Prosthetic Platform Ø: 4.3 mm, 5.5 mm Gingival Height: 1-5 mm Angle: 0° Indexed, Non-Indexed Titanium Alloy (ASTM F136), anodized						EZ Post Abutment Prosthetic Platform Ø: 4-7 mm Gingival Height: 1-5 mm Angle: 0°, Indexed, Non-Indexed Ti-6A1-4V ELI, anodized						
NanoPost Angled Abutments	Prosthetic Platform Ø: 4.3 mm Gingival Height: 1-5 mm Angle: 7.5°, 15° Indexed Titanium Alloy (ASTM F136), anodized						Angled Abutment Prosthetic Platform Ø: 4-7 mm Gingival Height: 1-5 mm Angle: 15°, 25° Indexed & Non-Indexed Ti-6A1-4V ELI, anodized, non-anodized						
UniPost Abutments	Prosthetic Platform Ø: 4.3 mm Gingival Height: 1-5 mm Threaded Titanium Alloy (ASTM F136), anodized										EZ Post Abutments Ø: 5.0-7.0 mm Gingival Height: 1-5 mm Solid Abutments Ø: 5.0-7.0 mm Gingival Height: 1-5 mm	Low Profile Abutments Prosthetic Post Height: 2.2 mm	

Feature	Subject Device	Primary Predicate Device	Reference Devices										
	K120414	K123988	K170392	K163194	K192347	K182448	K200992	K131644	K153509	K152787	K092341	K203355
	Kontact Dental Implant System	OsseoSpeed™ Plus	AnyRidge Octa 1 Implant System	S.I.N. Dental Implant System	Neodent Implant System - GM Line	ST Internal Implant System	AnyRidge Octa 1 Implant System	S.I.N. Dental Implant System	Ankylos SynCone® Abutment 5°	GPS® Angled Abutment	ST Internal Fixture System	Low Profile Abutment	Straumann TLX Novaloc and Cementable Abutments
	Biotech Dental, SAS	Astra Tech AB	MegaGen Implant Co., Ltd	S.I.N. - Sistema de Implante Nacional S.A.	JJGC Industria e Comercio de Materiais Dentarios SA	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd	S.I.N. - Sistema de Implante Nacional S.A.	Dentsply International, Incorporated	Implant Direct Sybron Manufacturing, LLC	T-Plus Implant Tech. Co., Ltd.	Biomet 3i, Inc.	Institut Straumann AG
Conical Abutments	Prosthetic Platform Ø: 4.0 mm, 4.9 mm Gingival Height: 1-5 mm Angle: 0°, 17° Indexed, Non-Indexed Titanium Alloy (ASTM F136), anodized						Prosthetic Platform Ø: 4-5 mm Gingival Height: 1-5 mm Angle: 0°, 17°, 30° Indexed, Non-Indexed Ti-6A1-4V ELI, anodized, non-anodized					Low Profile Abutments Angle: 0° Gingival Height: 1-5 mm Angle: 17° Gingival Height: 1-4 mm	
IsoPost Abutments	Overdenture Type Gingival Height: 1.5-5 mm Angle: 0°, 7.5°, 15°, 22° Non-Indexed Titanium Alloy (ASTM F136), anodized								Overdenture Type GH: 1.5-4.5 mm Angle: 0°, 7.5°, 15°, 22.5°, 30° Indexed Titanium Alloy (ASTM F136)	Overdenture Type Gingival Height: 1.5-5 mm Angle: 0° Indexed Ti-6A1-4V ELI, TiN coated			Novaloc Abutments Angle: 0° Gingival Height: 1-6 mm Angle 15° Gingival Height: 2-6 mm
Ball Abutments	Overdenture Type Gingival Height: 1-5 mm Ball Ø: 2.25 mm Non-Indexed Titanium Alloy (ASTM F136)	Ball Abutments Gingival Height: 1-7 mm Ball Ø 2.25 mm Non-Indexed Titanium (ASTM F67)											
How Provided													
Sterility	Non-Sterile; Sterile (Cover Screws)	Sterilize	Non-Sterile	Sterilize	Sterile	Non-Sterile	Non-Sterile	Sterilize	Non-Sterile	Non-Sterile			
Sterilization Method	Moist Heat; Gamma Irradiation	Gamma Irradiation	Moist Heat	Gamma Irradiation	Ethylene Oxide Exposure	Moist Heat	Moist Heat	Gamma Irradiation	Moist Heat	Moist Heat			
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use			