January 5, 2024

Terrats Medical SL
% Kevin Thomas
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K233316
Trade/Device Name: DESS Dental Smart Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 2, 2024
Received: January 2, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

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

510(k) Number *(if known)*

K233316

Device Name

DESS Dental Smart Solutions

Indications for Use (Describe)

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

Compatible Implant Systems

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	2.52
Astra Tech EV	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Internal	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Camlog	3.8	3.8
	4.3	4.3
Dentium SuperLine	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3
FRIADENT XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace Conical NobelParallel Conical	3.5	NP
	4.3, 5.0	RP
NobelReplace®	3.5	NP
	4.3	RP
	5.0	WP
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem TS Hiossen TS	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Straumann BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN
	4.8	WN
Zimmer Screw Vent® Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
TSX™ Implant System	3.7, 4.1, 4.7	3.5
	5.4, 6.0	4.5

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K233316
Terrats Medical SL
DESS Dental Smart Solutions

January 2, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 Barberà del Vallès 08210 Barcelona, Spain
Telephone	+34 935 646 006
Official Contact	Roger Terrats, CEO
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	DESS Dental Smart Solutions
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K170588, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K191986, DESS Dental Smart Solutions, Terrats Medical SL
K212628, DESS Dental Smart Solutions, Terrats Medical SL
K222288, DESS Dental Smart Solutions, Terrats Medical SL
K212538, DESS Dental Implants, Terrats Medical SL
K231434, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices for OEM implant body clearances
K140347, ANKYLOS C/X Implant System, Dentsply International Inc.
K120414, OsseoSpeed™ Plus, Astra Tech AB
K111287, Astra Tech Implant System Plus, Astra Tech AB
K101732, Astra Tech Implant System, Astra Tech AB
K042429, BioHorizons The Prodigy System™ Endosseous Implants, BioHorizons Implant Systems, Inc.
K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implant Systems, Inc.
K093321, BioHorizons Laser-Lok 3.0 Implant System, BioHorizons Implant Systems, Inc.
K063341, 3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc.
K083496, CAMLOG Implant System Modified Implants and Abutments, Altatec GmbH
K160965, SuperLine, Dentium Co., Ltd.
K073075, FRIADENT Implant Systems (FRIALIT® plus Dental Implant System, XiVE® S plus Dental Implant System, XiVE® TG plus Dental Implant System, ANKYLOS® plus Dental Implant System), Dentsply International Inc.
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários SA
K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K201225, Neodent Implant System – GM Helix Implants 7.0, JJGC Indústria e Comércio de Materiais Dentários S.A.
K142260, NobelActive®, Nobel Biocare AB
K173418, NobelParallel™ Conical Connection, Nobel Biocare AB
K050705, TiUnite Implants®, Nobel Biocare AB
K050406, NOBELSPEEDY™ Implants, Nobel Biocare USA LLC
K050258, Groovy Implants, Nobel Biocare AB
K023113, Replace TiUnite Endosseous Implant, Nobel Biocare USA, Inc.
K161604, OSSTEM Implant System, OSSTEM Implant Co., Ltd.
K173961, Straumann® BLX Implant System, Institut Straumann AG
K181703, Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments, Institut Straumann AG
K191256, Straumann BLX Ø3.5 mm Implants, Institut Straumann AG
K210855, Straumann BLX Implant System, Institut Straumann AG
K212533, BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants, Institut Straumann AG
K140878, Straumann® Bone Level Tapered Implants, Straumann USA, LLC
K130222, Straumann® Dental Implant System SLActive and Roxolid Product Families, Straumann USA, LLC
K013227, Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.
K072589, Tapered Screw-Vent Implant, 4.1mmD, Zimmer Dental, Inc.
K220978, TSX™ Implants, Biomet 3i LLC

The primary predicate device K170588, and the reference devices K191986, K212628, and K222288 are in support of substantial equivalence of the subject device designs, material, manufacturing, and biocompatibility. The reference device K212538 is in support of substantial equivalence of the subject device sterilization, packaging, and shelf life.

INDICATIONS FOR USE STATEMENT

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

Compatible Implant Systems

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	2.52
Astra Tech EV	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Internal	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Camlog	3.8	3.8
	4.3	4.3
Dentium SuperLine	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3
FRIADENT XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace Conical NobelParallel Conical	3.5	NP
	4.3, 5.0	RP
NobelReplace®	3.5	NP
	4.3	RP
	5.0	WP
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem TS Hiossen TS	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Straumann BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN
	4.8	WN
Zimmer Screw Vent® Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
TSX™ Implant System	3.7, 4.1, 4.7	4.5
	5.4, 6.0	4.5

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions abutment system by a change in sterilization status to provide products sterile to the end user that were previously cleared to be provided non-sterile. The subject device abutments and abutment screws were cleared previously to be provided non-sterile to the end user in K170588, K191986, K212628, and K222288. All subject device components will now be provided sterile.

The subject device components include Healing Abutments, Temporary Abutments, Multi-Unit Abutments (0°, 17°, and 30°), and abutment screws. A summary of the subject components is provided in the following table.

	Subject Device Components				
OEM Implant Lines	**Healing Abutments**	**Temporary Abutments**	**Munti-Unit Abutments, 0°**	**Munti-Unit Abutments, 17° and 30°**	**Screws**
Ankylos C/X	**X**	**X**			**X**
Astra Tech EV	**X**	**X**	**X**	**X**	**X**
Astra Tech OsseoSpeed™	**X**	**X**	**X**	**X**	**X**
BioHorizons Internal	**X**		**X**		
Biomet 3i Certain®	**X**	**X**			**X**
Biomet 3i OSSEOTITE®	**X**	**X**	**X**		**X**
Camlog	**X**	**X**			**X**

	Subject Device Components				
OEM Implant Lines	**Healing Abutments**	**Temporary Abutments**	**Munti-Unit Abutments, 0°**	**Munti-Unit Abutments, 17° and 30°**	**Screws**
Dentium SuperLine			X		
FRIADENT XiVE®	X	X			X
Neodent Grand Morse			X	X	
NobelActive® NobelReplace Conical NobelParallel Conical	X	X	X	X	X
NobelReplace®	X	X	X		X
Nobel Brånemark System®	X	X	X		X
Osstem TS Hiossen TS		X	X		X
Straumann BLX	X		X	X	
Straumann® Bone Level	X	X	X	X	X
Straumann® Tissue Level	X	X	X		X
Zimmer Screw Vent® Tapered Screw-Vent®	X	X			X
TSX™ Implant System	X	X			X

Healing Abutments are compatible with the OEM implant lines as listed in this summary, and as protectors (healing attachments) for use with Straumann Converter Abutments (multi-unit abutment for Straumann Tissue Level implants) and for DESS Multi-Unit Abutments. The Healing Abutments are provided in a range of gingival heights from 1 mm to 6.5 mm, and in a range of coronal (maximum) diameters of 3.5 mm to 7 mm.

Temporary Abutments are compatible with the OEM implant lines as listed in this summary and are available for single-unit and multiple-unit restorations. Temporary Abutments are provided in a range of gingival heights from 0.35 mm to 2.5 mm, and in a range of prosthetic platform diameters from 4.5 mm to 6.8 mm.

Multi-Unit Abutments are compatible with the OEM implant lines as listed in this summary in straight (0°) and angled (17° and 30°) designs. Multi-Unit are provided in gingival heights from 1 mm to 6 mm for the straight (0°) designs, 2.5 mm to 4.5 mm for angled 17° designs, and 3.5 mm to 5.5 mm for the angled 30° designs.

Abutment screws are compatible with the OEM implant lines as listed in this summary. There are no changes to the design of the screws cleared previously in K170588, K212628, K191986, and K222288.

The subject device abutments and abutment screws have the same OEM implant compatibilities as the identical screws cleared in K170588, K212628, K191986, and K222288.

PERFORMANCE DATA

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- non-clinical analysis was performed to evaluate the subject devices (including all abutments, abutment screw, and materials) in the MR environment using scientific rationale and published literature (TO Woods, JG Delfino, and S Rajan, “Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices,” Journal of Testing and Evaluation, Volume 49, No. 2, 2021, pp. 783-795); the analysis addressed parameters per the FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (issued May 2021) including magnetically induced displacement force and torque;
- referenced from K212538 was gamma irradiation sterilization validation to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to ISO 11137-1 and ISO 11137-2; bacterial endotoxin testing including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 to demonstrate that all sterile product meets a limit of < 20 EU/device; and shelf life testing of samples after

accelerated aging equivalent to five (5) years of real time aging according to ASTM F1980, with testing of the packaging sterile barrier and sterility testing of product;

- referenced from K170588 was moist heat sterilization validated by the overkill method to a sterility assurance level (SAL) of 10^{-6} according to ISO 17665-1 and ISO/TR 17665-2;
- referenced from K170588, K191986, K212628, and K222288 was biocompatibility of the subject device components;
- referenced from K170588, K191986, K212628, and K222288 was compatibility of the subject abutments and the OEM implants listed in the Indications for Use Statement.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

All subject device components are identical in design, material, and technological characteristics to those of the primary predicate device K170588, and the reference devices K191986, K212628, and K222288.

The subject device abutments have similar or identical ranges abutment-implant platform diameter, prosthetic platform diameter, gingival height, and angulation as the components cleared in the predicate device K170588, and the reference devices K191986, K212628, and K222288. The subject device screws are identical to the screws previously cleared in K170588, K191986, K212628, and K222288.

The subject device abutments have the same compatibilities as previously cleared in the primary predicate device K170588 and in the reference devices K191986, K212628, and K222288.

All subject device components are provided sterile by gamma irradiation and are packaged in a PETG blister with a Tyvek® lid. The gamma sterilization, packaging, and 5-year shelf life for sterile devices is the same as that validated in the reference device K212538. Subject devices that are provided non-sterile are packaged in PETG blister packs or PET bags.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, identical or nearly identical technological characteristics, and are made of the same material. The subject device and the primary predicate device 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.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Devices	Reference Device	Reference Device	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K170588 DESS Dental Smart Solutions Terrats Medical SL	K191986 DESS Dental Smart Solutions Terrats Medical SL	K212628 DESS Dental Smart Solutions Terrats Medical SL	K222288 DESS Dental Smart Solutions Terrats Medical SL
Product Code	NHA	NHA	NHA	NHA	NHA
Reason for predicate/reference	n/a	Abutment designs, OEM compatibilities, manufacturing	Abutment designs, OEM compatibilities, manufacturing	Abutment designs, OEM compatibilities, manufacturing	Abutment designs, OEM compatibilities, manufacturing
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Indications for Use Statement	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. *The complete Indications for Use Statement with OEM implant compatibilities is provided in this Summary.*	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with TiBase or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K170588.*	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with Ti Base abutments or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K1191986.*	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K212628.*	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K222288.*
Designs	Healing Abutments	Healing Abutments	Healing Abutments	Healing Abutments	Healing Abutments
	Temporary Abutments	Temporary Abutments	Temporary Abutments		Temporary Abutments
	Multi-unit Abutments, Straight	Multi-unit Abutments, Straight		Multi-unit Abutments, Straight	Multi-unit Abutments, Straight
	Multi-unit Abutments, Angled 17° and 30°		Multi-unit Abutments, Angled 17° and 30°		Multi-unit Abutments, Angled 17° and 30°
	Prosthetic components for Multi-unit Abutments	Prosthetic components for Multi-unit Abutments			
	Screws	Screws	Screws	Screws	Screws
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Abutment/Implant Platform Ø, mm	2.52 – 5.7	3.4 – 5.7	2.52 – 6.0	2.3 – 6.0	2.52 – 6.5
Prosthetic Platform Ø, mm	4.5 – 6.8	4.5 – 6.8	4.5 – 6.5	4.5 – 6.5	4.5 – 6.5
Abutment Angle	0°, 17°, 30°	0°	0°, 17°, 30°	0°	0°, 17°, 30°
Material					
Abutment Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V alloy (ASTM F136)	Ti-6Al-4V alloy (ASTM F136)	Ti-6Al-4V alloy (ASTM F136)	Ti-6Al-4V alloy (ASTM F136)
Abutment Surface	Anodization and a SelectGrip® surface	Anodization and a SelectGrip® surface	Anodization and a SelectGrip® surface	Anodization and a SelectGrip® surface	Anodization and a SelectGrip® surface
Screw Material	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy DLC coating
How Provided					
Sterilization	Sterile by gamma irradiation Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use