10/27/2022

Terrats Medical SL
% Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K222288
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: July 29, 2022
Received: July 29, 2022

Dear Melissa Burbage:

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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K222288

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.

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.

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™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons	3.0, 3.4, 3.8	3.0
	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
	5.0	5.0
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
	5.5	5.5
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive®, NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
NobelReplace® Trilobe	3.5	NP
	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem 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	NNC, RN
	4.1	RN
	4.8	RN, WN
Zimmer Eztetic	3.1	2.9

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
Zimmer Spline	3.25,	3.25
	3.75, 4.0	3.75/4.0
	5.0	5.0
Zimmer SwissPlus	3.7	3.8
	4.8	4.8

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

K222288

Terrats Medical SL
DESS® Dental Smart Solutions

October 27, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 08210 Barberà del Vallès Barcelona, Spain
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Representative/Consultant	Melissa Burbage, BS Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email mburbage@paxmed.com flarson@paxmed.com kthomas@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 Products Panel
Reviewing Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device

K170588, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices

K173908, DESS Dental Smart Solutions, Terrats Medical SL
K191986, DESS Dental Smart Solutions, Terrats Medical SL
K203464, DESS Dental Smart Solutions, Terrats Medical SL
K212577, DESS Dental Smart Solutions, Terrats Medical SL

K212628, DESS Dental Smart Solutions, Terrats Medical SL
K160965, SuperLine, Dentium Co., LTD.
K082639, Dental Tapered SwissPlus Implant, Zimmer Dental, Inc.
K013494, Spline Twist Implant, Sulzer Dental, Inc.
K012055, Spline Twist Implant, Sulzer Dental, Inc.
K142082, Zimmer 3.1mmD Dental Implant System, Zimmer Dental, Inc.

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.

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.

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™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons	3.0, 3.4, 3.8	3.0
	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
	5.0	5.0
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
	5.5	5.5
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive®, NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
NobelReplace® Trilobe	3.5	NP
	4.3	RP

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem 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	NNC, RN
	4.1	RN
	4.8	RN, WN
Zimmer Eztetic	3.1	2.9
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
Zimmer Spline	3.25,	3.25
	3.75, 4.0	3.75/4.0
	5.0	5.0
Zimmer SwissPlus	3.7	3.8
	4.8	4.8

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions abutment system cleared under K170588, K173908, K191986, K203464, K212577, and K212628 to:

- include new OEM platform compatibilities (that have not been previously cleared) for previously cleared DESS designs,
- include previously-cleared OEM platform compatibilities for previously-cleared DESS abutment designs for which the specific combinations of compatibility and design were not cleared previously,
- add angulation to previously cleared Ti Base Abutments, Pre-Milled Blank, Ti, and Multi Unit Abutment,
- include a new abutment design, ZRN Multi Unit Abutment,
- include additional gingival height variations for the Ti Base Interface and DESSLoc Abutment,
- include two attachments: Interface Attachment for UniAbutment and Bar Attachment.

This submission includes five (5) abutment designs [Healing Abutments, Temporary Abutments, Multi Unit Abutments (straight and angled), ZRN Multi Unit Abutments (straight and angled), and DESSLoc Abutments], one (1) abutment blank (Pre-Milled Blank, Ti), three (3) base designs (Ti Base, C-Base, CrCo Base), two (2) attachments, and twenty (20) screws.

This submission includes one (1) new abutment design (ZRN Multi Unit abutment), based on the previously cleared Multi Unit abutment, but with an added zirconium nitride (ZrN) coating. The identical coating is used on the DESSLoc Abutments that have been cleared in K170588, K191986, and K212628.

This submission includes two attachments. The subject device Interface Attachment for UniAbutment attaches directly to the UniAbutments and is similar to the Interface Attachment for UniAbutment in

K170588. The subject device DESSLoc for Bar is designed to attached directly to the bar. The top portion of this attachment has the same design and material as the DESSLoc abutment cleared in K170588, K191986, and K212628.

The subject device includes the addition of new and previously cleared OEM compatibilities to previously cleared abutment design (Healing Abutments, Temporary Abutments, Ti Base, C-Base, CrCo Base, Pre-Milled Blank Ti, Multi Unit abutments, and DESSLoc abutment). New compatibility is introduced for four (4) implant systems for which Terrats Medical has no prior clearance, for a total of eleven (11) new platforms. The direct correlation between each subject device design and the corresponding compatible implant platforms is shown in *Summary of Subject Device Components and Implant Platforms for Compatible Implant Systems*.

The subject device DESS Dental Smart Solutions provides a range of prosthetic solutions for dental implant restoration. DESS abutments, bases and blanks are offered in a variety of connection types to enable compatibility with currently marketed dental implants. Abutments are provided with the appropriate abutment screw (if applicable) for attachment to the corresponding implant, and the appropriate prosthetic screw (if applicable) for attachment of a screw-retained prosthesis. All abutments and screws are provided non-sterile.

Healing Abutment
Healing Abutments are designed to cover the implant connection during the period between implant placement and final abutment placement. Healing Abutments are provided in multiple gingival heights to aid in contouring the gingiva during healing. All healing abutments are marked to identify their gingival height and compatible implant platform. Healing abutments are made of titanium alloy (Ti-6Al-4V). Healing abutments that are the subject of this submission are identical to those cleared under K170588, K191986, and K212628 but are provided for one (1) additional platform compatibility.

Temporary Abutment
Temporary Abutments are designed with horizontal grooves and a vertical flat portion to aid in the fabrication of temporary restorations. They can be reduced in height to adapt to individual patient occlusion. Temporary Abutments are not intended for angle correction. In addition, Temporary Abutments have a SelectGrip® surface to aid in bonding retention. SelectGrip is a sandblasted surface treatment process that significantly improves bonding strength between the treated abutment surface and the cemented prosthesis. Temporary Abutments are available for single-unit and multiple-unit restorations, the former with engaging connections to the implants and the latter with non-engaging connections. Temporary abutments are made of titanium alloy (Ti-6Al-4V). Healing abutments that are the subject of this submission are identical to those cleared under K170588 and K191986 but are provided for one (1) additional platform compatibility.

Base Abutments
Subject device Bases, including Ti Base Interface, C- Base, and CrCo Base, are designed for custom abutment fabrication of a CAD/CAM zirconia superstructure on which a crown may be placed. They are two-piece abutments for which the second part (or top half) is the ceramic superstructure. They also may be used for support of a crown directly on the abutment.

All patient-specific custom abutment fabrication for Bases is by prescription on the order of the clinician. All zirconia superstructures for use with the subject device Bases will be made at a Terrats Medical validated milling center under FDA quality system regulations, and the material will conform to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).*

The design parameters for the CAD/CAM zirconia superstructure to be used on Ti Base Interface compatible with all implants except those listed in the next paragraph are identical to those previously cleared in K170588, K191986, and K212628. They are:

Minimum wall thickness – 0.4 mm
Minimum post height – 4.2 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

For the CAD/CAM zirconia superstructure to be used on Ti Base Interface compatible with Biomet 3i Certain, NobelReplace Trilobe, and Zimmer Screw-Vent/Tapered Screw-Vent (except for 3.3 mm implants), the following design parameters may be used:

Minimum wall thickness – 0.4 mm
Minimum post height – 4.2 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Maximum angulation of the final abutment – 30°

The design parameters for the CAD/CAM zirconia superstructure to be used on C-Base are identical to those cleared in K203464. They are:

Minimum wall thickness – 0.4 mm
Minimum post height – 4.7 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

The design parameters for the CAD/CAM zirconia superstructure to be used on CrCo Base are identical to those cleared in K173908 and K191986. They are:

Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restorations – 4.5 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

Pre-Milled Blank, Ti

Pre-milled Blank Abutments are available in engaging designs. They are made of titanium alloy (Ti-6Al-4V). Subject device Pre-milled (Blank) Abutments are identical to Pre-milled Blank Abutments cleared in K170588, K191986, K212628, and K212577.

The design parameters for the CAD/CAM fabrication of custom abutments from Pre-milled Blank Ti compatible with all implants except those listed in the next paragraph are identical to those cleared in K170588, K191986, and K212628. They are:

Minimum wall thickness – 0.45 mm
Minimum post height – 4.0 mm
Maximum gingival height – 6.0 mm
Minimum gingival height – 0.3 mm
Pre-Milled Blanks are for straight abutments only

The design parameters for the CAD/CAM Pre-milled Blanks that are compatible with Astra Tech EV (except for 3.0 mm implants), Astra Tech OssesSpeed, Biomet 3i Certain, Nobel Active/Nobel Parallel Conical (except for 3.0 mm implants), NobelReplace Trilobe, Nobel Branemark, Straumann Bone Level, and Zimmer Screw-Vent/Tapered Screw-Vent (except 3.3 mm implants) are identical to those cleared in K212577. They are:

Minimum wall thickness – 0.45 mm
Minimum post height – 4.0 mm
Maximum gingival height – 6.0 mm
Minimum gingival height – 0.3 mm
Maximum angulation of the final abutment - 30°

Multi Unit Abutment

Multi Unit Abutment is designed for attachment of multi-unit screw-retained restorations and is provided in straight and angled designs. The design is the same as that of the Multi Unit Abutments cleared in K170588, K191986, and K212628 and the abutment is made from the same titanium alloy (Ti-6Al-4V). A new abutment line, Multi Unit Abutment ZRN, is being introduced. This subject device abutment has exactly the same design as the Multi Unit Abutment with an added coating of zirconium nitride (ZrN) to the top portion of the abutment. This coating is identical to the ZrN coating used on the DESSLoc Abutments that have been cleared in K170588, K191986, and K212628. Dedicated titanium alloy screws coated with Diamond-like carbon (DLC) are available to attach the abutment to the implant and a dedicated titanium alloy prosthetic screw is available to attach the restoration to the abutment. The subject device Interface Attachment for UniAbutment attaches directly to the UniAbutments and is similar to the Interface Attachment for UniAbutment in K170588.

DESSLoc® Abutment

DESSLoc Abutment is designed for overdenture attachment. It is identical to the DESS LOC Abutment cleared in K170588, K191986, and K212628, except that additional gingival heights and new OEM Combabilities are provided. DESSLoc Abutments are made of titanium alloy (Ti-6Al-4V) and have a zirconium nitride (ZrN) coating.

Screws

DESS Dental Smart Solutions screws are designed to attach the abutment to the implant or the prosthesis to the abutment. There are twenty (20) new screws for the subject device components with similar designs to those of screws cleared in K170588, K173908, K191986, K203464, K212577, and K212628. Two (2) of these new screws are variations that are being used with the already cleared components. The subject device screw 19.349 has same connection and thread mating as screws cleared in K191986, and 19.102 has the same connection and thread mating as screws cleared in K170588. Screws are available with and without a DLC (Diamond-like Carbon) coating. DLC coating is a polycrystalline tungsten carbide/carbon and chromium coating that is identical to the DLC coating on screws cleared in K170588.

Summary of Subject Device Components and Implant Platforms for Compatible Implant Systems

Compatible Implant Systems	DESS Abutment System	Healing Abutment	Temporary Abutment	Ti Base Interface, Engaging and non-engaging	C-Base, Engaging and non-engaging	CrCo Base, Engaging and non-engaging	Pre-milled Blank Ti, Engaging	Multi Unit Abutment	Multi Unit ZRN	DESSLoc Abutment	**Screws**
Ankylos C/X	Internal ANK	2.52	2.52	2.52 (0°)	2.52 (0°)	2.52 (0°)	2.52 (0°)			2.52	**X**
Astra Tech EV	Conic EVO	3.0, 3.6, 4.2, 4.8, 5.4	3.6, 4.2, 4.8	3.0, 3.6, 4.2, 4.8, 5.4 (0°)	3.6, 4.2, 4.8 (0°)	3.6, 4.2, 4.8 (0°)	3.0 (0°), 3.6, 4.2, 4.8, 5.4 **(30°)**	**3.0 (0°),** 3.6, 4.2, 4.8, **5.4 (0°, 17°, 30°)**	**3.0 (0°), 3.6, 4.2, 4.8, 5.4 (0°, 17°, 30°)**	3.6, 4.2, 4.8	**X**
Astra Tech OsseoSpeed	Internal Hex Conic	3.5/4.0, 4.5/5.0	3.5/4.0, 4.5/5.0	3.5/4.0, 4.5/5.0 (0°)	3.5/4.0, 4.5/5.0 (0°)	3.5/4.0, 4.5/5.0 (0°)	3.0 (0°), 3.5/4.0, 4.5/5.0 **(30°)**	3.5/4.0, 4.5/5.0 (0°, **17°, 30°**)	**3.5/4.0, 4.5/5.0 (0°, 17°, 30°)**	**3.0, 3.5/4.0, 4.5/5.0**	**X**
BioHorizons Internal	Internal Hex BH	**3.5, 4.5, 5.7**		3.5, 4.5, 5.7 (0°)	**3.5, 4.5, 5.7 (0°)**		3.5, 4.5, 5.7 (0°)	**3.5, 4.5 (0°)**	**3.5, 4.5 (0°)**	3.5, 4.5, 5.7	**X**
Biomet 3i Certain	Internal Hex "Click"	3.4, 4.1, 5.0	3.4, 4.1, 5.0	3.4, 4.1, 5.0 **(30°)**	3.4, 4.1, 5.0 (0°)	3.4, 4.1, 5.0 (0°)	3.4, 4.1, 5.0 **(30°)**			**3.4, 4.1, 5.0**	**X**
Biomet 3i OSSEOTITE	External Hex USA	3.4, 4.1, 5.0	3.4, 4.1, 5.0	3.4, 4.1, 5.0 (0°)	3.4, 4.1, 5.0 (0°)	3.4, 4.1, 5.0 (0°)	3.4, 4.1, 5.0 (0°)	3.4, 4.1, 5.0 (0°)	**3.4, 4.1, 5.0 (0°)**	**3.4, 4.1, 5.0**	
Camlog	Internal CAM	3.8, 4.3, 5.0	3.8, 4.3, 5.0	3.8, 4.3, 5.0 (0°)		3.8, 4.3, 5.0 (0°)	3.8, 4.3, 5.0 (0°)			3.8, 4.3, 5.0	
Dentium SuperLine	**DENT**							**3.3 (0°)**	**3.3 (0°)**		
FRIADENT XiVE	Internal Hex FD	3.4, 3.8, 4.5	3.4, 3.8, 4.5	3.4, 3.8, 4.5, **5.5** (0°)	3.4, 3.8, 4.5 (0°)	3.4, 3.8, 4.5 (0°)	3.4, 3.8, 4.5 (0°)			3.4, 3.8, 4.5	
Megagen AnyRidge	Conic Anyr			**3.5 (0°)**	3.5 (0°)						**X**
Neodent Grand Morse	Neo GM			Grand Morse (0°)	Grand Morse (0°)			Grand Morse (0°, **17°, 30°**)	**Grand Morse (0°, 17°, 30°)**		**X**
NobelActive®, NobelParallel Conical	Active Hex	NP, RP	NP, RP	3.0, NP, RP, WP (0°)	NP, RP, WP (0°)	NP, RP (0°)	3.0 (0°), NP, RP, WP (30°)	NP, RP (0°, 17°, 30°)	**NP, RP (0°, 17°, 30°)**	NP, RP	**X**
NobelReplace Trilobe	Tri-lobe	NP, RP, WP	NP, RP, WP	NP, RP, WP, 6.0 **(30°)**	NP, RP, WP, 6.0 (0°)	NP, RP, WP (0°)	NP, RP, WP, 6.0 **(30°)**	NP, RP, WP (0°)	**NP, RP, WP (0°)**	NP, RP	**X**
Nobel Branemark System	External Hex Universal	NP, RP, WP	NP, RP, WP	NP, RP, WP (0°)	NP, RP, WP (0°)	NP, RP, WP (0°)	NP, RP, WP, 6.0 **(30°)**	NP, RP, WP (0°)	**NP, RP, WP (0°)**	**NP**, RP, **WP**	

Compatible Implant Systems	DESS Abutment System	Healing Abutment	Temporary Abutment	Ti Base Interface, Engaging and non-engaging	C-Base, Engaging and non-engaging	CrCo Base, Engaging and non-engaging	Pre-milled Blank Ti, Engaging	Multi Unit Abutment	Multi Unit ZRN	DESSLoc Abutment	**Screws**
Osstem TS	Conic OSS		**Mini, Regular**	Mini, Regular (0°)	Mini, Regular (0°)	**Mini, Regular (0°)**	**Mini, Regular (0°)**	**Mini, Regular (0°)**	**Mini, Regular (0°)**		
Straumann BLX	Conical BLX	RB/WB, WB		RB/WB, WB (0°)			RB/WB, WB (0°)	RB/WB (0°, **17°, 30°**)	**RB/WB (0°, 17°, 30°)**		**X**
Straumann Bone Level	Conical BL	NC, RC	NC, RC	NC, RC (0°)	NC, RC (0°)	NC, RC (0°)	NC, RC (30°)	NC, RC (0°, 17°, 30°)	**NC, RC (0°, 17°, 30°)**	NC, RC	**X**
Straumann Tissue Level	Octagon	RN, WN	RN, WN	NNC, RN, WN (0°)	NNC, RN, WN (0°)	RN, WN (0°)	NNC, RN, WN (0°)			RN, WN	**X**
Zimmer Eztetic	**Internal EZ**									**2.9**	
Zimmer Screw Vent / Tapered Screw Vent	Internal Hex USA	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5, 4.5, 5.7 **(30°)**	3.5, 4.5, 5.7 (0°)	3.5, 4.5, 5.7 (0°)	3.5, 4.5, 5.7 (30°)	3.5 (0°, 17°, 30°) 4.5 (0°, **17°, 30°**)	**3.5, 4.5 (0°, 17°, 30°)**	3.5, 4.5, **5.7**	**X**
Zimmer Spline	**External SPL**									**3.25, 3.75/4.0, 5.0**	
Zimmer SwissPlus	**Internal Swiss**									**2.5, 3.0**	

Bold indicates new components

COMPATIBLITIES

All compatibilities are identical to those of the primary predicate K170588 and additional predicate K173908, K191986, K203464, K212577, K212628, except for the addition of compatibilities with four (4) new systems, eleven (11) platforms, for Dentium SuperLine, Zimmer Eztetic, Zimmer Spline, and Zimmer SwissPlus.

Compatible Implant Systems

Compatible Implant System	Implant 510(k)	Implant 510(k) Name	Manufacturer
Ankylos C/X	K140347	Ankylos C/X Implant System	DENTSPLY International, Inc.
Astra Tech EV	K111287	Astra Tech Implant System	Astra Tech AB
	K120414	OsseoSpeed Plus	
Astra Tech OsseoSpeed	K101732	OsseoSpeed™	Astra Tech AB
BioHorizons Internal	K042429	The Prodigy System Dental Implants	BioHorizons Implants System, Inc.
	K071638	BioHorizons Tapered Internal Implant System	
Biomet 3i Certain®	K063341	3i OSSEOTITE Certain® Dental Implants	Implant Innovations, Inc.
Biomet 3i OSSEOTITE	K063286	OSSEOTITE® Dental Implants	Implant Innovations, Inc.
Camlog	K083496	Camlog Implant System	Altatech GmbH
Dentium SuperLine	K160965	SuperLine	Dentium Co., Ltd
Friadent XiVE	K073075	Friadent Implant Systems	DENTSPLY International, Inc.
MegaGen AnyRidge	K110955	AnyRidge Internal Implant System	Megagen Co., Ltd.
Neodent Grand Morse	K163194	Neodent Implant System – GM Line	JJGC Industria E Comercio De Materials Dentarios SA
NobelActive, NobelParallel Conical	K142260	NobelActive®	Nobel Biocare AB
	K102436	NobelActive 3.0	
	K073142	NobelReplace Hexagonal Implants	
Nobel-Replace Tri-Lobe	K050705	TiUnite Implants	Nobel Biocare AB
	K050406	NobelSpeedy Implants	
Nobel Brånemark	K022562	Various Brånemark System Implants– Immediate Function Indication	Nobel Biocare AB
OSSTEM TS	K161604	Osstem Implant System	OSSTEM IMPLANT Co., Ltd
Straumann BLX	K173961	Straumann BLX Implant System	Institut Straumann AG
Straumann Bone Level	K140878	Straumann® Bone Level Tapered Implants	Straumann USA, LLC
Straumann Tissue Level	K130222	Straumann® Dental Implant System SLActive and Roxolid Product Families	Straumann USA, LLC
Zimmer Eztetic	K142082	Zimmer 3.1mm Dental Implant	Zimmer Dental, Inc.
Zimmer Screw-Vent / Tapered Screw-Vent	K011028	Screw-Vent Dental Implant System	Sulzer Dental, Inc.
	K112160	Tapered Screw-Vent® X Implant	Zimmer Dental, Inc.
Zimmer Spline	K012055	3.25mm Spline Twist Implant	Sulzer Dental, Inc.
	K013494	3.75mm and 5.0mm Spline Twist Implant	
Zimmer SwissPlus	K082639	Zimmer Tapered SwissPlus Implants	Zimmer Dental, Inc.

MATERIAL COMPOSITION

All subject device abutments and screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401*) or from Co-Cr-Mo alloy (CrCo) conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*.

Zirconia superstructures for Ti Base, C-Base, and CrCo Base are made of Y-TZP conforming to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*. The cement recommended in labeling for bonding of superstructures is Multi Link Hybrid Abutment Cement from Ivoclar Vivadent AG, cleared under K130436. All of these materials are equivalent to those cleared in K170588, K173908, K191986, and K203464.

All subject device components are manufactured from the same materials, are treated with the same surface treatments (SelectGrip surface, DLC coating and anodization), and are manufactured in the same facilities using the same manufacturing processes as corresponding devices cleared in K170588, K173908, K191986, K203464, K212577, and K212628.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 14937, and biocompatibility according to ISO 10993-5 and ISO 10993-12, leveraged from K170588, K173908, K191986, K203464, K212577, and K212628; and reverse engineering analysis of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility for new OEM connections. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

All subject device abutments are identical in design, materials and technological characteristics to corresponding abutments of the primary predicate K170588 and additional predicates K173908, K191986, K203464, K212577, K212628. The subject device Multi Unit Abutment ZRN are substantially equivalent to Multi Unit abutments cleared in primary predicate K170588 and additional predicates K191986, and K212628, except that it has a zirconium nitride (ZrN) coating added to the top portion of the abutment. This coating is used on the DESSLoc Abutments that have been cleared in primary predicate K170588 and additional predicates K191986 and K212628.

The SelectGrip® surface on Ti Base Interface is identical to the SelectGrip surface on equivalent abutments cleared in primary predicate K170588. The ZrN coating on DESSLoc and Multi Unit ZRN Abutment is identical to that on DESS LOC Abutments cleared in primary predicate K170588 and additional predicate K191986 and K212628.

The cement recommended in labeling for bonding of superstructures is Multi-Link cement from Ivoclar Vivadent, cleared under K130436. This is the same cement recommended in labeling for the primary predicate K170588 and the additional predicates K173908, K191986, and K212628.

All screws are identical in design, materials and technological characteristics to those cleared in primary predicate K170588 and additional predicates K173908, K191986, K203464, K212577, K212628 except for threads that accommodate the new compatibilities. Diamond-like carbon (DLC) coatings that are available on certain screws are identical to those on screws cleared in primary predicate K170588 and additional predicates K173908, K191986, K203464, K212577, K212628.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate, and additional predicate 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.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Additional Predicate Devices
	DESS Dental Smart Solutions Terrats Medical SL	K170588 DESS Dental Smart Solutions Terrats Medical SL	K173908, K191986, K203464, K212577, K212628 DESS Dental Smart Solutions Terrats Medical SL
Indications	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. *For complete Indications for Use statement on OEM Compatibility see Section 4.*	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. *For complete Indications for Use statement on OEM Compatibility see 510(k) Summary for K170588 in Section 12.*	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. *For complete Indications for Use statement on OEM Compatibility see 510(k) Summaries for K173908, K191986, K203464, K212577, K212628 in Section 12.*
Design			
Designs	Healing, Temporary Abutment, Ti Base, C-base, CrCo Base, Pre-milled Blank, Multi Unit Abutment, Multi Unit ZRN Abutment, DESSLoc	Healing, Temporary, Straight, Multi-unit, Locator-type, CAD/CAM Bases, CAD/CAM Blanks	Healing, Temporary, Straight, Uniabutment, Multi-unit, DESSLoc, CAD/CAM Bases, CAD/CAM Blanks,Ti Bases, CrCo Base, Pre-milled (Blank)
Prosthesis Attachment	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
Abutment/Implant Platform Diameter, mm	2.52 – 6.5	2.52 – 6.5	2.3 – 6.0
Prosthetic Platform Diameter, mm	4.5-6.5	4.5	4.0 – 6.5
Abutment Angle	0°, 17°, 30°	Straight (0°)	0°, 17°, 30°
Abutment/ Implant Interface	Internal, External	Internal, External	Internal, External
Material			
Abutments	Ti-6Al-4V ELI Co-Cr-Mo Alloy	Ti-6Al-4V ELI	Ti-6Al-4V ELI Co-Cr-Mo Alloy
Screws	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating