



March 11, 2022

Terrats Medical SL
% Floyd Larson
President
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K212628
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: February 8, 2022
Received: February 9, 2022

Dear Floyd Larson:

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

Indications for Use

510(k) Number (if known) K212628

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 DESS Bases or Blanks 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
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
FRIADENT XiVE®	3.8	3.8
	4.5	4.5
	5.5	5.5
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	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
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
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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
PRASStaff@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
Terrats Medical SL
DESS® Dental Smart Solutions

March 10, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 08210 Barberà del Vallès Barcelona, Spain
Telephone	+34 935 646 006
Official Contact	Roger Terrats, CEO
Representative/Consultant	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 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

Reference Devices for New OEM Compatibilities

All compatibilities are identical to those of the primary predicate K170588 and the reference devices K173908 and K191986, except for the addition of compatibilities with three (3) new systems, seven (7) platforms, for BioHorizons, Neodent Grand Morse and Straumann BLX, and the addition of two (2) new platforms for Astra Tech EV previously cleared in K191986.

510(k)	Compatible Implant	Manufacturer
K111287, K120414	Astra Tech EV (Cleared as OsseoSpeed Plus)	Dentsply Sirona Inc.
K042429 K071638	BioHorizons	BioHorizons Implant Systems, Inc.
K163194	Neodent Grand Morse	JJGC Indústria e Comércio de Materiais Dentários S.A.
K173961	Straumann BLX	Institut Straumann AG

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 DESS Bases or Blanks 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
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
FRIADENT XiVE®	3.8	3.8
	4.5	4.5
	5.5	5.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name
NobelActive®, NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
NobelReplace® Trilobe	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
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
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions abutment system cleared under K170588, K173908 and K191986 to add additional components for previously cleared OEM platform compatibilities and to add additional OEM platform compatibilities for previously cleared DESS designs. This submission includes three (3) abutments (Healing Abutments, straight Multi Unit Abutments and DESSLoc Abutments), three (3) bases, two (2) blanks, and seven (7) screws.

Among the subject devices for this submission are abutments and screws compatible with three (3) implant systems for which Terrats Medical has no prior clearance and one (1) implant system for which new platform compatibilities are included, for a total of nine (9) new platforms.

The direct correlation between each subject device design and the corresponding compatible implant platforms is shown in the table *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. All abutments are provided non-sterile and each abutment is supplied with the appropriate abutment screw (if applicable) for attachment to the corresponding implant.

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 but are provided for four (4) additional platform compatibilities.

Ti Bases

Subject device Ti Bases, including Ti Base Interface, DESS Aurum Base and ELLIPTIBase, 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 Ti Bases (Ti Base Interface, DESS Aurum Base and ELLIPTIBase) is by prescription on the order of the clinician. All zirconia superstructures for use with the subject device Ti Base Interface, DESS Aurum Base and ELLIPTIBase 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 are identical to those cleared in K170588. 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.

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

Compatible Implant Systems	DESS Abutment System	Healing Abutment	Ti Base Interface, Engaging	Ti Base Interface, Non-engaging	DESS Aurum Base, Engaging	DESS Aurum Base, Non-engaging	ELLIPTIBase, Engaging	Pre-milled Blank Ti, Engaging	Pre-milled Blank CrCo, Engaging	Multi Unit Abutment	DESSLoc Abutment	Screws
<i>Description: See Section 10.1.x</i>		<i>10.1.1</i>	<i>10.1.2</i>				<i>10.1.3</i>			<i>10.1.4</i>	<i>10.1.5</i>	<i>10.1.6</i>
Astra Tech EV	Conic EVO	3.0, 5.4	5.4	5.4			3.0	3.0, 3.6, 4.2, 4.8, 5.4	5.4	3.6, 4.2, 4.8		
Astra Tech OsseoSpeed	Internal Hex Conic		3.0, 3.5/4.0, 4.5/5.0	3.0, 3.5/4.0, 4.5/5.0				3.0, 3.5/4.0, 4.5/5.0		3.5/4.0, 4.5/5.0		
BioHorizons Internal	BH Internal		3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.0	3.5, 4.5, 5.7				X
Biomet 3i Certain	Internal Hex Click							4.1, 5.0			3.4, 4.1, 5.0	
Biomet 3i OSSEOTITE	External Hex USA				3.4, 4.1	3.4, 4.1					3.4, 4.1, 5.0	
Camlog	Internal CAM							3.8, 4.3, 5.0				
FRIADENT XiVE	Internal Hex FD							3.8, 4.5, 5.5	5.5			
Neodent Grand Morse	Neo GM		Grand Morse	Grand Morse	Grand Morse	Grand Morse		Grand Morse	Grand Morse	Grand Morse		X
NobelActive, NobelParallel Conical	Active Hex		NP, RP	NP, RP			3.0					X
NobelReplace Trilobe	Tri-lobe							RP, WP, 6.0				
Nobel Branemark System	External Hex Universal				NP, RP	NP, RP						
Osstem TS	Conic OSS							Mini, Regular				
Straumann BLX	Conical BLX	RB/WB, WB	RB/WB, WB	RB/WB, WB	RB/WB, WB	RB/WB, WB		RB/WB, WB	WB	RB/WB		X
Straumann Bone Level	Conical BL		NC, RC	NC, RC			NC					
Straumann Tissue Level	Octagon						NNC		NNC			
Zimmer Screw Vent / Tapered Screw Vent	Internal Hex USA						3.5				3.5, 4.5, 5.7	

DESS Aurum Base is available in an engaging design and a non-engaging design and ELLIPTIBase is available in an engaging design. Before attachment of the zirconia superstructure or crown, the DESS Aurum Base and ELLIPTIBase post height is 3.0 mm. When used for a single-unit restoration the DESS Aurum Base and ELLIPTIBase are to be used with a superstructure to create a minimum post height of 4.0 mm. DESS Aurum Base and ELLIPTIBase are made of titanium alloy (Ti-6Al-4V) with a gold anodized surface.

Design of ELLIPTIBase is similar to that of Ti Base (DESS Aurum) cleared in K173908, except that the post portion is not rotationally symmetric, being elliptical in cross-section.

When the DESS Aurum Base or ELLIPTIBase is used with a zirconia superstructure, design parameters for the zirconia superstructure are:

- Minimum wall thickness – 0.4 mm
- Minimum post height for single-unit restorations – 4.0 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 and Pre-milled Blank CrCo

Pre-milled Blanks are designed for custom abutment fabrication by a CAD/CAM process and are available in an engaging design. All patient-specific custom abutment fabrication is by prescription on the order of the clinician. Pre-milled Blank is made of titanium alloy (Ti-6Al-4V) or of Co-Cr-Mo Alloy (CrCo).

The design parameters for the CAD/CAM fabrication of custom abutments from Pre-milled Blank Ti and Pre-milled Blank CrCo are:

- Minimum wall thickness – 0.45 mm
- Minimum post height for single-unit restorations – 4.0 mm
- Minimum gingival height – 0.5 mm
- Maximum gingival height – 6.0 mm
- All Pre-milled Blank Ti and Pre-milled Blank CrCo are for straight abutments only.

Manufacture of CAD/CAM custom abutments from Pre-milled Blank Ti and Pre-milled Blank CrCo is to be performed at a Terrats Medical validated milling center.

Multi Unit Abutment

Multi Unit Abutment is designed for attachment of multi-unit screw-retained restorations and is provided in a straight design. 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.

DESSLoc[®] Abutment

DESSLoc Abutment is designed for overdenture attachment. It is identical to the DESS LOC Abutment cleared in K170588, except that additional gingival heights 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. For previously cleared compatibilities, the screws that were cleared in K170588, K173908 and K191986 for each compatibility are used. For new compatibilities, four (4)

subject device screws are included. Screws are available with and without a DLC (Diamond-like Carbon) coating.

MATERIAL COMPOSITION

All subject device abutments and screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)* or from Co-Cr-Mo alloy conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*. Zirconia superstructures for Ti Base Interface, DESS Aurum Base and ELLIPTIBase 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 cement from Ivoclar Vivadent, cleared under K130436. All of these materials are identical to those of the primary predicate device K170588 and the reference devices K173908 and K191986.

PERFORMANCE DATA

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

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

Subject device abutments are substantially equivalent in intended use to the primary predicate device cleared in K170588 and the reference devices cleared in K173908 and K191986. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K170588, except for the list of compatible OEM implants.

All subject device abutments are identical in design, materials and technological characteristics to those of the primary predicate K170588 and the reference devices K173908 and K191986, except for variations in gingival height and the elliptical shape of the ELLIPTIBase post. Abutments with gingival heights of 1.5 mm, 3.0 mm and greater are in common use in dental implant systems such as compatible system Astra Tech EV, cleared in K111287. Subject device DESS Aurum Base is identical in design, materials and technological characteristics to Aurum Abutments cleared in reference device K173908. The SelectGrip® surface on all Ti Bases is identical to the SelectGrip surface on equivalent abutments cleared in primary predicate K170588 and reference devices K173908 and K191986. The gold anodized surface on Ti Base (DESS Aurum) is identical to the anodized surface on Aurum Abutments of the reference device K173908. The ZrN coating on DESSLoc is identical to that on DESS LOC Abutments cleared in primary predicate K170588.

All screws are identical in design, materials and technological characteristics to those cleared in primary predicate K170588 except for threads that accommodate the new compatibilities. Diamond-like carbon (DLC) coatings on screws are identical to those on screws cleared in primary predicate K170588.

Substantial equivalence of new compatibilities is supported by compatibility analysis.

Digital files for all CAD/CAM superstructures or abutments from blanks must be sent to a validated milling center for manufacture. DESS Ti Base Interface, DESS Aurum Base, ELLIPTIBase and Pre-milled Blanks are for fabrication of straight custom abutments only.

The subject device is to be sterilized by the end-user, the same as primary predicate device K170588 and reference devices K173908 and K191986.

All of the subject device components are manufactured from the same materials and in the same facilities using the same manufacturing processes as used for the Terrats Medical components previously cleared in K170588, K173908 and K191986. Therefore, no new biocompatibility testing has been performed, as the subject device is substantially equivalent to the predicate devices in K170588, K173908 and K191986 with regard to materials and processing.

Minor differences in the designs, dimensions, sizes, or compatible OEM implant lines among the subject device, the primary predicate device, and the reference devices do not affect substantial equivalence. These minor differences do not impact substantial equivalence because these differences are related to the compatible OEM implant designs.

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.

Table of Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement																																																																																																									
<p>Subject Device</p> <p>DESS Dental Smart Solutions</p>	<p>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.</p> <p>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.</p>																																																																																																									
<p>Terrats Medical SL</p>	<p style="text-align: center;">Compatible Implant Systems</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th data-bbox="431 470 773 516">Compatible Implant System</th> <th data-bbox="773 470 1146 516">Implant Body Diameter, mm</th> <th data-bbox="1146 470 1468 516">Implant Platform Name</th> </tr> </thead> <tbody> <tr> <td data-bbox="431 516 773 667" rowspan="5">Astra Tech EV</td> <td data-bbox="773 516 1146 548" style="text-align: center;">3.0</td> <td data-bbox="1146 516 1468 548" style="text-align: center;">3.0</td> </tr> <tr> <td data-bbox="773 548 1146 579" style="text-align: center;">3.6</td> <td data-bbox="1146 548 1468 579" style="text-align: center;">3.6</td> </tr> <tr> <td data-bbox="773 579 1146 611" style="text-align: center;">4.2</td> <td data-bbox="1146 579 1468 611" style="text-align: center;">4.2</td> </tr> <tr> <td data-bbox="773 611 1146 642" style="text-align: center;">4.8</td> <td data-bbox="1146 611 1468 642" style="text-align: center;">4.8</td> </tr> <tr> <td data-bbox="773 642 1146 674" style="text-align: center;">5.4</td> <td data-bbox="1146 642 1468 674" style="text-align: center;">5.4</td> </tr> <tr> <td data-bbox="431 674 773 758" rowspan="3">Astra Tech OsseoSpeed™</td> <td data-bbox="773 674 1146 705" style="text-align: center;">3.0</td> <td data-bbox="1146 674 1468 705" style="text-align: center;">3.0</td> </tr> <tr> <td data-bbox="773 705 1146 737" style="text-align: center;">3.5/4.0</td> <td data-bbox="1146 705 1468 737" style="text-align: center;">3.5/4.0</td> </tr> <tr> <td data-bbox="773 737 1146 758" style="text-align: center;">4.5/5.0</td> <td data-bbox="1146 737 1468 758" style="text-align: center;">4.5/5.0</td> </tr> <tr> <td data-bbox="431 758 773 873" rowspan="4">BioHorizons</td> <td data-bbox="773 758 1146 789" style="text-align: center;">3.0, 3.4, 3.8</td> <td data-bbox="1146 758 1468 789" style="text-align: center;">3.0</td> </tr> <tr> <td data-bbox="773 789 1146 821" style="text-align: center;">3.8, 4.6</td> <td data-bbox="1146 789 1468 821" style="text-align: center;">3.5</td> </tr> <tr> <td data-bbox="773 821 1146 852" style="text-align: center;">4.6, 5.8</td> <td data-bbox="1146 821 1468 852" style="text-align: center;">4.5</td> </tr> <tr> <td data-bbox="773 852 1146 873" style="text-align: center;">5.8</td> <td data-bbox="1146 852 1468 873" style="text-align: center;">5.7</td> </tr> <tr> <td data-bbox="431 873 773 957" rowspan="3">Biomet 3i Certain®</td> <td data-bbox="773 873 1146 905" style="text-align: center;">3.25</td> <td data-bbox="1146 873 1468 905" style="text-align: center;">3.4</td> </tr> <tr> <td data-bbox="773 905 1146 936" style="text-align: center;">4.0</td> <td data-bbox="1146 905 1468 936" style="text-align: center;">4.1</td> </tr> <tr> <td data-bbox="773 936 1146 957" style="text-align: center;">5.0</td> <td data-bbox="1146 936 1468 957" style="text-align: center;">5.0</td> </tr> <tr> <td data-bbox="431 957 773 1052" rowspan="3">Biomet 3i OSSEOTITE®</td> <td data-bbox="773 957 1146 989" style="text-align: center;">3.25</td> <td data-bbox="1146 957 1468 989" style="text-align: center;">3.4</td> </tr> <tr> <td data-bbox="773 989 1146 1020" style="text-align: center;">3.75, 4.0</td> <td data-bbox="1146 989 1468 1020" style="text-align: center;">4.1</td> </tr> <tr> <td data-bbox="773 1020 1146 1052" style="text-align: center;">5.0</td> <td data-bbox="1146 1020 1468 1052" style="text-align: center;">5.0</td> </tr> <tr> <td data-bbox="431 1052 773 1136" rowspan="3">Camlog</td> <td data-bbox="773 1052 1146 1083" style="text-align: center;">3.8</td> <td data-bbox="1146 1052 1468 1083" style="text-align: center;">3.8</td> </tr> <tr> <td data-bbox="773 1083 1146 1115" style="text-align: center;">4.3</td> <td data-bbox="1146 1083 1468 1115" style="text-align: center;">4.3</td> </tr> <tr> <td data-bbox="773 1115 1146 1136" style="text-align: center;">5.0</td> <td data-bbox="1146 1115 1468 1136" style="text-align: center;">5.0</td> </tr> <tr> <td data-bbox="431 1136 773 1220" rowspan="3">FRIADENT XiVE®</td> <td data-bbox="773 1136 1146 1167" style="text-align: center;">3.8</td> <td data-bbox="1146 1136 1468 1167" style="text-align: center;">3.8</td> </tr> <tr> <td data-bbox="773 1167 1146 1199" style="text-align: center;">4.5</td> <td data-bbox="1146 1167 1468 1199" style="text-align: center;">4.5</td> </tr> <tr> <td data-bbox="773 1199 1146 1220" style="text-align: center;">5.5</td> <td data-bbox="1146 1199 1468 1220" style="text-align: center;">5.5</td> </tr> <tr> <td data-bbox="431 1220 773 1251">Neodent Grand Morse</td> <td data-bbox="773 1220 1146 1251" style="text-align: center;">3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0</td> <td data-bbox="1146 1220 1468 1251" style="text-align: center;">Grand Morse (GM)</td> </tr> <tr> <td data-bbox="431 1251 773 1346" rowspan="3">NobelActive®, NobelParallel Conical</td> <td data-bbox="773 1251 1146 1283" style="text-align: center;">3.0</td> <td data-bbox="1146 1251 1468 1283" style="text-align: center;">3.0</td> </tr> <tr> <td data-bbox="773 1283 1146 1314" style="text-align: center;">3.5</td> <td data-bbox="1146 1283 1468 1314" style="text-align: center;">NP</td> </tr> <tr> <td data-bbox="773 1314 1146 1346" style="text-align: center;">4.3, 5.0</td> <td data-bbox="1146 1314 1468 1346" style="text-align: center;">RP</td> </tr> <tr> <td data-bbox="431 1346 773 1430" rowspan="3">NobelReplace® Trilobe</td> <td data-bbox="773 1346 1146 1377" style="text-align: center;">4.3</td> <td data-bbox="1146 1346 1468 1377" style="text-align: center;">RP</td> </tr> <tr> <td data-bbox="773 1377 1146 1409" style="text-align: center;">5.0</td> <td data-bbox="1146 1377 1468 1409" style="text-align: center;">WP</td> </tr> <tr> <td data-bbox="773 1409 1146 1430" style="text-align: center;">6.0</td> <td data-bbox="1146 1409 1468 1430" style="text-align: center;">6.0</td> </tr> <tr> <td data-bbox="431 1430 773 1493" rowspan="2">Nobel Brånemark System®</td> <td data-bbox="773 1430 1146 1461" style="text-align: center;">3.3</td> <td data-bbox="1146 1430 1468 1461" style="text-align: center;">NP</td> </tr> <tr> <td data-bbox="773 1461 1146 1493" style="text-align: center;">3.75, 4.0</td> <td data-bbox="1146 1461 1468 1493" style="text-align: center;">RP</td> </tr> <tr> <td data-bbox="431 1493 773 1556" rowspan="2">Osstem TS</td> <td data-bbox="773 1493 1146 1524" style="text-align: center;">3.5</td> <td data-bbox="1146 1493 1468 1524" style="text-align: center;">Mini</td> </tr> <tr> <td data-bbox="773 1524 1146 1556" style="text-align: center;">4.0, 4.5, 5.0, 6.0, 7.0</td> <td data-bbox="1146 1524 1468 1556" style="text-align: center;">Regular</td> </tr> <tr> <td data-bbox="431 1556 773 1619" rowspan="2">Straumann BLX</td> <td data-bbox="773 1556 1146 1587" style="text-align: center;">3.5, 3.75, 4.0, 4.5</td> <td data-bbox="1146 1556 1468 1587" style="text-align: center;">RB</td> </tr> <tr> <td data-bbox="773 1587 1146 1619" style="text-align: center;">5.0, 5.5, 6.5</td> <td data-bbox="1146 1587 1468 1619" style="text-align: center;">WB</td> </tr> <tr> <td data-bbox="431 1619 773 1671">Straumann® Bone Level</td> <td data-bbox="773 1619 1146 1650" style="text-align: center;">3.3</td> <td data-bbox="1146 1619 1468 1650" style="text-align: center;">NC</td> </tr> <tr> <td data-bbox="431 1671 773 1703" rowspan="2">Straumann® Tissue Level</td> <td data-bbox="773 1671 1146 1703" style="text-align: center;">4.1/4.8</td> <td data-bbox="1146 1671 1468 1703" style="text-align: center;">RC</td> </tr> <tr> <td data-bbox="773 1703 1146 1734" style="text-align: center;">3.3</td> <td data-bbox="1146 1703 1468 1734" style="text-align: center;">NNC</td> </tr> <tr> <td data-bbox="431 1734 773 1787" rowspan="3">Zimmer Screw Vent®/ Tapered Screw-Vent®</td> <td data-bbox="773 1734 1146 1766" style="text-align: center;">3.3, 3.7, 4.1</td> <td data-bbox="1146 1734 1468 1766" style="text-align: center;">3.5</td> </tr> <tr> <td data-bbox="773 1766 1146 1787" style="text-align: center;">4.7</td> <td data-bbox="1146 1766 1468 1787" style="text-align: center;">4.5</td> </tr> <tr> <td data-bbox="773 1787 1146 1808" style="text-align: center;">6.0</td> <td data-bbox="1146 1787 1468 1808" style="text-align: center;">5.7</td> </tr> </tbody> </table>	Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name	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	FRIADENT XiVE®	3.8	3.8	4.5	4.5	5.5	5.5	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	4.3	RP	5.0	WP	6.0	6.0	Nobel Brånemark System®	3.3	NP	3.75, 4.0	RP	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	Straumann® Tissue Level	4.1/4.8	RC	3.3	NNC	Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5	4.7	4.5	6.0	5.7
Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name																																																																																																								
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																																																																																																								
FRIADENT XiVE®	3.8	3.8																																																																																																								
	4.5	4.5																																																																																																								
	5.5	5.5																																																																																																								
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	4.3	RP																																																																																																								
	5.0	WP																																																																																																								
	6.0	6.0																																																																																																								
Nobel Brånemark System®	3.3	NP																																																																																																								
	3.75, 4.0	RP																																																																																																								
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																																																																																																								
Straumann® Tissue Level	4.1/4.8	RC																																																																																																								
	3.3	NNC																																																																																																								
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5																																																																																																								
	4.7	4.5																																																																																																								
	6.0	5.7																																																																																																								

<p>Primary Predicate Device</p> <p>K170588, DESS Dental Smart Solutions Terrats Medical SL</p>	<p>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.</p> <p>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.</p> <p style="text-align: center;">Compatible Implant Systems</p> <table border="1" data-bbox="431 394 1463 743"> <thead> <tr> <th>Implant System Compatibility</th> <th>Implant Diameter (mm)</th> <th>Platform Diameter (mm)</th> </tr> </thead> <tbody> <tr> <td>3i Certain®</td> <td>3.25, 4.0, 5.0</td> <td>3.4, 4.1, 5.0</td> </tr> <tr> <td>3i OSSEOTITE®</td> <td>3.25, 3.75, 4.0, 5.0</td> <td>3.4, 4.1, 5.0</td> </tr> <tr> <td>OsseoSpeed™</td> <td>3.5, 4.0, 5.0</td> <td>3.5/4.0, 4.5/5.0</td> </tr> <tr> <td>FRIADENT XiVE</td> <td>3.4, 3.8, 4.5</td> <td>3.4, 3.8, 4.5</td> </tr> <tr> <td>NobelActive®</td> <td>3.5, 4.3, 5.0</td> <td>NP, RP</td> </tr> <tr> <td>NobelReplace Conical</td> <td>3.5, 4.3, 5.0</td> <td>NP, RP</td> </tr> <tr> <td>Nobel Replace Trilobe</td> <td>3.5, 4.3, 5.0</td> <td>NP, RP, WP</td> </tr> <tr> <td>Brånemark</td> <td>3.5, 3.75/4.0, 5.0</td> <td>NP, RP, WP</td> </tr> <tr> <td>Straumann® Bone Level</td> <td>3.3, 4.1, 4.8</td> <td>NC, RC</td> </tr> <tr> <td>Straumann® Tissue Level</td> <td>3.3, 4.1, 4.8</td> <td>RN, WN</td> </tr> <tr> <td>Tapered Screw-Vent®</td> <td>3.7, 4.1, 4.7, 6.0</td> <td>3.5, 4.5, 5.7</td> </tr> </tbody> </table>	Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)	3i Certain®	3.25, 4.0, 5.0	3.4, 4.1, 5.0	3i OSSEOTITE®	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0	OsseoSpeed™	3.5, 4.0, 5.0	3.5/4.0, 4.5/5.0	FRIADENT XiVE	3.4, 3.8, 4.5	3.4, 3.8, 4.5	NobelActive®	3.5, 4.3, 5.0	NP, RP	NobelReplace Conical	3.5, 4.3, 5.0	NP, RP	Nobel Replace Trilobe	3.5, 4.3, 5.0	NP, RP, WP	Brånemark	3.5, 3.75/4.0, 5.0	NP, RP, WP	Straumann® Bone Level	3.3, 4.1, 4.8	NC, RC	Straumann® Tissue Level	3.3, 4.1, 4.8	RN, WN	Tapered Screw-Vent®	3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)																																			
3i Certain®	3.25, 4.0, 5.0	3.4, 4.1, 5.0																																			
3i OSSEOTITE®	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0																																			
OsseoSpeed™	3.5, 4.0, 5.0	3.5/4.0, 4.5/5.0																																			
FRIADENT XiVE	3.4, 3.8, 4.5	3.4, 3.8, 4.5																																			
NobelActive®	3.5, 4.3, 5.0	NP, RP																																			
NobelReplace Conical	3.5, 4.3, 5.0	NP, RP																																			
Nobel Replace Trilobe	3.5, 4.3, 5.0	NP, RP, WP																																			
Brånemark	3.5, 3.75/4.0, 5.0	NP, RP, WP																																			
Straumann® Bone Level	3.3, 4.1, 4.8	NC, RC																																			
Straumann® Tissue Level	3.3, 4.1, 4.8	RN, WN																																			
Tapered Screw-Vent®	3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7																																			
<p>Reference Device</p> <p>K173908 DESS Dental Smart Solutions Terrats Medical SL</p>	<p>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.</p> <p>All digitally designed custom abutments for use with Aurum™ Abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.</p> <p style="text-align: center;">Compatible Implant Systems</p> <table border="1" data-bbox="431 894 1463 1285"> <thead> <tr> <th>Implant System Compatibility</th> <th>Implant Body</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr> <td>3i Certain®</td> <td>3.25, 4.0, 5.0</td> <td>3.4, 4.1, 5.0</td> </tr> <tr> <td>3i OSSEOTITE®</td> <td>3.25, 3.75, 4.0, 5.0</td> <td>3.4, 4.1, 5.0</td> </tr> <tr> <td>OsseoSpeed™</td> <td>3.5, 4.0, 5.0</td> <td>3.5/4.0, 4.5/5.0</td> </tr> <tr> <td>FRIADENT XiVE</td> <td>3.4, 3.8, 4.5</td> <td>3.4, 3.8, 4.5</td> </tr> <tr> <td>NobelActive®</td> <td>3.5, 4.3, 5.0</td> <td>NP, RP</td> </tr> <tr> <td>NobelReplace® Conical</td> <td>3.5, 4.3, 5.0</td> <td>NP, RP</td> </tr> <tr> <td>NobelReplace® Trilobe</td> <td>3.5, 4.3, 5.0</td> <td>NP, RP, WP</td> </tr> <tr> <td>Brånemark</td> <td>3.5, 3.75/4.0, 5.0</td> <td>NP, RP, WP</td> </tr> <tr> <td>Straumann® Bone Level</td> <td>3.3, 4.1, 4.8</td> <td>NC, RC</td> </tr> <tr> <td>Straumann® Tissue Level</td> <td>3.3, 4.1, 4.8</td> <td>RP, WP</td> </tr> <tr> <td>Tapered Screw-Vent®</td> <td>3.7, 4.1, 4.7, 6.0</td> <td>3.5, 4.5, 5.7</td> </tr> </tbody> </table>	Implant System Compatibility	Implant Body	Implant Platform	3i Certain®	3.25, 4.0, 5.0	3.4, 4.1, 5.0	3i OSSEOTITE®	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0	OsseoSpeed™	3.5, 4.0, 5.0	3.5/4.0, 4.5/5.0	FRIADENT XiVE	3.4, 3.8, 4.5	3.4, 3.8, 4.5	NobelActive®	3.5, 4.3, 5.0	NP, RP	NobelReplace® Conical	3.5, 4.3, 5.0	NP, RP	NobelReplace® Trilobe	3.5, 4.3, 5.0	NP, RP, WP	Brånemark	3.5, 3.75/4.0, 5.0	NP, RP, WP	Straumann® Bone Level	3.3, 4.1, 4.8	NC, RC	Straumann® Tissue Level	3.3, 4.1, 4.8	RP, WP	Tapered Screw-Vent®	3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Implant System Compatibility	Implant Body	Implant Platform																																			
3i Certain®	3.25, 4.0, 5.0	3.4, 4.1, 5.0																																			
3i OSSEOTITE®	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0																																			
OsseoSpeed™	3.5, 4.0, 5.0	3.5/4.0, 4.5/5.0																																			
FRIADENT XiVE	3.4, 3.8, 4.5	3.4, 3.8, 4.5																																			
NobelActive®	3.5, 4.3, 5.0	NP, RP																																			
NobelReplace® Conical	3.5, 4.3, 5.0	NP, RP																																			
NobelReplace® Trilobe	3.5, 4.3, 5.0	NP, RP, WP																																			
Brånemark	3.5, 3.75/4.0, 5.0	NP, RP, WP																																			
Straumann® Bone Level	3.3, 4.1, 4.8	NC, RC																																			
Straumann® Tissue Level	3.3, 4.1, 4.8	RP, WP																																			
Tapered Screw-Vent®	3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7																																			

Reference Device

K191986
DESS Dental Smart
Solutions
Terrats Medical SL

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,	Implant Platform
Ankylos C/X	3.5, 4.5, 5.5	2.52 mm
Astra Tech EV	3.6	2.9 mm
	4.2	3.5 mm
	4.8	4.1 mm
	3.0	3.0 mm
Astra Tech OsseoSpeed™	3.5/4.0	3.5/4.0 mm
	4.5/5.0	4.5/5.0 mm
	3.25	3.45 mm
Biomet 3i Certain®	4.0	4.1 mm
	5.0	5.0 mm
	3.25	3.4 mm
Biomet 3i OSSEOTITE®	3.75, 4.0	4.1 mm
	5.0	5.0 mm
	3.3	3.3 mm
Camlog	3.8	3.8 mm
	4.3	4.3 mm
	5.0	5.0 mm
	3.4	3.4 mm
FRIADENT XiVE®	3.8	3.8 mm
	4.5	4.5 mm
	5.5	5.5 mm
	3.5, 4.0, 4.5, 5.0, 5.5	3.5 mm
MegaGen AnyRidge	3.0	3.0 (3.0 mm)
	3.5	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
NobelActive®, NobelParallel Conical	3.5	NP (3.5 mm)
	4.3	RP (4.3 mm)
	5.0	WP (5.0 mm)
	6.0	6.0 (6.0 mm)
NobelReplace® Trilobe	3.3	NP (3.5 mm)
	3.75, 4.0	RP (4.1 mm)
	5.0	WP (5.1 mm)
Nobel Brånemark System®	3.5	Mini (2.8 mm)
	4.0, 4.5, 5.0, 6.0, 7.0	Regular (3.35 mm)
	3.3	NC (3.3 mm)
Straumann® Bone Level	4.1/4.8	RC (4.1/4.8 mm)
	3.3	NNC (3.5 mm)
Straumann® Tissue Level	3.3, 4.1, 4.8	RN (4.8 mm)
	4.8	WN (6.5 mm)
	3.3, 3.7, 4.1	3.5 mm
Zimmer Screw Vent®/ Tapered Screw-Vent®	4.7	4.5 mm
	6.0	5.7 mm

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Reference Devices	
	DESS Dental Smart Solutions Terrats Medical SL	K170588 DESS Dental Smart Solutions Terrats Medical SL	K173908 DESS Dental Smart Solutions Terrats Medical SL	K191986 DESS Dental Smart Solutions Terrats Medical SL
Design				
Designs	Healing, Ti Base Interface, DESS Aurum Base, ELLIPTIBase, Pre-milled Blank, Multi Unit, DESSLoc	Healing, Temporary, Straight, Multi-unit, Locator-type, CAD/CAM Bases, CAD/CAM Blanks,	CAD/CAM Bases, CAD/CAM Blanks,	Healing, Temporary, Straight, Uniabutment, Multi-unit, DESSLoc, Ti Base (Interface), Ti Base (DESS Aurum), CrCo Base, Pre-milled (Blank)
Prosthesis Attachment	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
Abutment/Implant Platform Diameter, mm	2.3 – 6.0	3.0 – 6.0	3.6 - 5.0	2.3 – 6.0
Prosthetic Platform Diameter, mm	4.5-6.5	4.5	4.0 – 6.5	4.5-6.5
Abutment Angle	Straight (0°)	Straight (0°)	Straight (0°)	0°, 17°, 30°
Abutment/ Implant Interface	Internal, External	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	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	Ti-6Al-4V ELI DLC coating