November 10, 2019

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

Re: K191986
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: October 9, 2019
Received: October 11, 2019

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

Enclosure

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

November 9, 2019

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 Barberà del Vallès 08210 Barcelona, Spain Telephone +34 935 646 006 Fax +34 935 647 317
Official Contact	Roger Terrats, COO
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin 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
K170588, DESS Dental Smart Solutions, Terrats Medical ST

Reference Devices
K173908, DESS Dental Smart Solutions, Terrats Medical SL
K161416, Multi-Unit Abutment Plus, Nobel Biocare AB

Compatible Implant Systems		
K140347	Ankylos C/X	Dentsply Sirona
K111287, K120414	Astra Tech EV (Cleared as OsseoSpeed Plus)	Dentsply Sirona
K101732	Astra Tech OsseoSpeed™	Dentsply Sirona
K063341	Biomet 3i Certain®	Zimmer Biomet Dental
K063286	Biomet 3i OSSEOTITE® Implant System	Zimmer Biomet Dental
K083496	Camlog	CAMLOG Biotechnologies AG
K073075	FRIADENT XiVE®	Dentsply Sirona
K110955	MegaGen AnyRidge	MegaGen Implant Co., Ltd.
K142260, K102436	NobelActive®, NobelParallel Conical	Nobel Biocare
K050705, K050406	NobelReplace® Trilobe	Nobel Biocare
K022562	Nobel Brånemark System®	Nobel Biocare
K161604	Osstem TS	Osstem Implant
K140878	Straumann® Bone Level	Institut Straumann AG
K130222	Straumann® Tissue Level	Institut Straumann AG
K011028, K112160	Zimmer Screw-Vent®/Tapered Screw-Vent®	Zimmer Biomet Dental

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

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions abutment system cleared under K170588 and K173908 to add additional components for previously cleared OEM platform compatibilities and to add additional OEM platform compatibilities for previously cleared DESS abutment designs. In total, this submission includes abutments compatible with 43 implant platforms from 16 OEM implant systems. Note that, because Nobel Active and NobelParallel Conical Connection implants share conical connection platforms, we have shown them as one system for purposes of this submission.

This submission includes abutments compatible with five (5) additional OEM implant systems (11 platforms) and abutments compatible with six (6) additional platforms for OEM implant system compatibilities that were cleared in K170588.

Additional subject device components for previously cleared compatibilities include addition of gingival heights of 1.5 mm and 3.0 mm for titanium bases and addition of 17° and 30° angled multi-unit abutments to the previously cleared straight multi-unit abutments.

Abutment designs and the correlation between each subject device abutment design and the corresponding compatible implant platforms are shown in **Table 1** *Summary of DESS Components and Abutment Platforms for Compatible Implant Systems*.

All abutments are provided non-sterile and each abutment is supplied with the appropriate abutment screw (if applicable) for attachment to the corresponding implant.

All subject device abutments 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 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)*. All ceramic components of the Ti Base abutments are composed of zirconia conforming to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).*

Table 1 Summary of DESS Components and Abutment Platforms for Compatible Implant Systems

Compatible Implant Systems	DESS Abutment System	Healing Abutment *(Titanium Alloy ASTM F136)*	Temporary Abutment, Engaging *(Titanium Alloy ASTM F136)*	Temporary Abutment, Non-engaging *(Titanium Alloy ASTM F136)*	Straight Abutment *(Titanium Alloy ASTM F136)*	Uniabutment *(Titanium Alloy ASTM F136)*	Multi-unit Abutment, Angled *(Titanium Alloy ASTM F136)*	DESSLoc® *(Titanium Alloy ASTM F136)*	Ti Base (Interface), Engaging *(Titanium Alloy ASTM F136)*	Ti Base (Interface), Non-engaging *(Titanium Alloy ASTM F136)*	Ti Base (DESS Aurum), Engaging *(Titanium Alloy ASTM F136)*	Ti Base (DESS Aurum), Non-engaging *(Titanium Alloy ASTM F136)*	CrCo Base, Engaging *(Co-Cr-Mo Alloy ASTM F1537)*	CrCo Base, Non-engaging *(Co-Cr-Mo Alloy ASTM F1537)*	Pre-milled (Blank) Abutment Ti, Engaging *(Titanium Alloy ASTM F136)*	Pre-milled (Blank) Abutment CrCo, Engaging *(Co-Cr-Mo Alloy ASTM F1537)*	Connection
Ankylos C/X	Internal Ank	2.52	2.52	2.52	2.52			2.52	2.52	2.52			2.52	2.52	2.52	2.52	Internal
Astra Tech EV	Conic Evo	2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1		2.9, 3.5, 4.1		2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1	2.9, 3.5, 4.1	Internal
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							Internal
Biomet 3i Certain®	Internal Hex Click								3.45, 4.1, 5.0	3.45, 4.1, 5.0							Internal
Biomet 3i OSSEOTITE®	External Hex USA								3.4, 4.1, 5.0	3.4, 4.1, 5.0							External
Camlog	Internal Cam	3.8, 4.3	3.8, 4.3	3.8, 4.3				3.8, 4.3	3.3, 3.8, 4.3, 5.0	3.3, 3.8, 4.3, 5.0	3.8, 4.3	3.8, 4.3	3.8, 4.3	3.8, 4.3	3.3, 3.8, 4.3, 5.0	3.3 3.8, 4.3, 5.0	Internal
FRIADENT XiVE®	Internal Hex FD								3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5							Internal
MegaGen AnyRidge	Conic Anyr								3.5	3.5	3.5	3.5			3.5	3.5	Internal
NobelActive® NobelParallel Conical	Active Hex						NP, RP		3.0, NP, RP, WP	3.0, NP, RP, WP					3.0, NP, RP, WP	WP	Internal
NobelReplace® Trilobe	Tri-Lobe								NP, RP, WP, 6.0	NP, RP, WP, 6.0					6.0	6.0	Internal
Nobel Brånemark System®	External Hex Universal								NP, RP, WP	NP, RP, WP							External

Compatible Implant Systems	DESS Abutment System	Healing Abutment *(Titanium Alloy ASTM F136)*	Temporary Abutment, Engaging *(Titanium Alloy ASTM F136)*	Temporary Abutment, Non-engaging *(Titanium Alloy ASTM F136)*	Straight Abutment *(Titanium Alloy ASTM F136)*	Uniabutment *(Titanium Alloy ASTM F136)*	Multi-unit Abutment, Angled *(Titanium Alloy ASTM F136)*	DESSLoc® *(Titanium Alloy ASTM F136)*	Ti Base (Interface), Engaging *(Titanium Alloy ASTM F136)*	Ti Base (Interface), Non-engaging *(Titanium Alloy ASTM F136)*	Ti Base (DESS Aurum), Engaging *(Titanium Alloy ASTM F136)*	Ti Base (DESS Aurum), Non-engaging *(Titanium Alloy ASTM F136)*	CrCo Base, Engaging (*Co-Cr-Mo Alloy ASTM F1537)*	CrCo Base, Non-engaging *(Co-Cr-Mo Alloy ASTM F1537)*	Pre-milled (Blank) Abutment Ti, Engaging *(Titanium Alloy ASTM F136)*	Pre-milled (Blank) Abutment CrCo, Engaging *(Co-Cr-Mo Alloy ASTM F1537)*	Connection
Osstem TS	Conic OSS								Mini, Regular	Mini, Regular	Mini, Regular	Mini, Regular			Mini, Regular	Mini, Regular	Internal
Straumann® Bone Level	Conical BL						NC, RC		NC, RC	NC, RC					NC, RC		Internal
Straumann® Tissue Level	Octagon								NNC	NNC					NNC, RN, WN		Internal
Zimmer Screw-Vent®/Tapered Screw-Vent®	Internal Hex USA						3.5		3.5, 4.5, 5.7	3.5, 4.5, 5.7					3.5		Internal

Ti Base (Interface) is a two-piece abutment designed for custom abutment fabrication with a CAD/CAM zirconia superstructure on which a crown may be placed. The ceramic superstructure produced through CAD/CAM is the second part of the two-piece abutment. The Ti Base may also support a ceramic Hybrid abutment in which the crown is included in the design of the abutment ceramic superstructure. The prosthetic post height is 4.2 mm. It is available in an engaging design and a non-engaging design. TiBase (Interface) is made of titanium alloy (Ti-6Al-4V) with a SelectGrip® surface. When used for a direct crown, TiBase (Interface) may be used with a POM burn out sleeve, which is available for laboratory fabrication of the prosthesis.

Designs of Ti Base (Interface) that are the subject of this submission are identical, including the SelectGrip surface, to those cleared under K170588, but are provided in gingival heights of 1.5 mm and 3.0 mm for implant connections cleared in K170588 and are provided for three (3) additional implant compatibilities (four systems) and additional platforms for systems cleared in K170855.

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
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

Ti Base (DESS Aurum) is a two-piece abutment used as a base that can be used for a direct multi-unit restoration or to support a CAD/CAM zirconia superstructure plus a single-unit or multi-unit restoration. The ceramic superstructure produced through CAD/CAM is the second part of the two-piece abutment. It is available in an engaging design and a non-engaging design. Before attachment of the zirconia superstructure or crown, the Ti Base (DESS Aurum) post height is 3.0 mm. When used for a single-unit restoration the Ti Base (DESS Aurum) is to be used with a superstructure to create a minimum post height of 4 mm. Ti Base (Aurum) is made of titanium alloy (Ti-6Al-4V) with a gold anodized surface. Abutments are colored gold by an anodization process in which the abutment is submerged in an electrolytic solution and exposed to an electric current to achieve the gold color.

Design of Ti Base (DESS Aurum), including the titanium alloy and the anodization treatment, is identical to that cleared as DESS Aurum Abutment in K173908, except that the subject device is provided in four additional implant system compatibilities as shown in **Table 11.12** *Ti Base (DESS Aurum), Engaging and Non-engaging*.

When the Ti Base (DESS Aurum) is used with a zirconia superstructure, design parameters for the zirconia superstructure are identical to those cleared in K173908. They are:

Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restorations – 4.0 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

All patient-specific custom abutment fabrication for TiBase (Interface) and Ti Base (DESS Aurum is by prescription on the order of the clinician. All zirconia superstructures for use with the subject device Ti Base (Interface) and Ti Base (Aurum) 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).*

DESS Dental Smart Solutions screws are designed to attach the abutment to the implant or the prosthesis to the abutment. Abutment screws for the DESS Abutment Systems Tri-Lobe and External Hex Universal, and prosthetic screws for Multi-unit Abutments are available with the DLC (Diamond-like

Carbon) coating to provide a low friction surface finish, designed to improve the preload of the screw and to produce a high clamping force between the abutment and the implant. This allows the clinician to apply less torque while achieving the same clamping force with the screw. DLC coating is a polycrystalline tungsten carbide/carbon and chromium coating that is identical to the DLC coating on screws cleared in K170588.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 14937; biocompatibility according to ISO 10993-5 and ISO 10993-12; reverse engineering analysis of OEM implant bodies, OEM abutment, and OEM abutment screws to confirm compatibility; and static compression and compression fatigue testing according to ISO 14801. 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 K161416. 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, with the exception of Multi-unit Abutments Angled, Ti Base (Interface) with gingival heights 1.5 mm and 3.0 mm and Ti Base (DESS Aurum). Subject device Multi-unit Abutments Angled are substantially equivalent in design, materials and technological characteristics to Multi-Unit Abutment Plus, cleared in reference device K161416. 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 Ti Base (DESS Aurum) is identical in design, materials and technological characteristics to Aurum Abutments cleared in reference device K173908. The SelectGrip® surface on Temporary Abutments, Straight Abutments and Ti Base (Interface) is identical to the SelectGrip surface on equivalent abutments cleared in primary predicate K170588. 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.

Substantial equivalence of Multi-unit Abutments Angled is supported by dynamic testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*.

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), Ti Base (DESS Aurum), CrCo Base, and Pre-milled Blank abutments 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 device K173908.

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 and K173908. Therefore, no new biocompatibility testing has been performed, as the subject device is substantially equivalent to the predicate devices in K170588 and K173908 with regards 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 or are mitigated by the mechanical performance testing.

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 2 Table of Substantial Equivalence – Indications for Use Statement

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device</td><td></td></tr>
<tr><td>DESS Dental Smart Solutions
Terrats Medical SL</td><td>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
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td>Ankylos C/X</td><td>3.5, 4.5, 5.5</td><td>2.52 mm</td></tr>
<tr><td rowspan="3">Astra Tech EV</td><td>3.6</td><td>2.9 mm</td></tr>
<tr><td>4.2</td><td>3.5 mm</td></tr>
<tr><td>4.8</td><td>4.1 mm</td></tr>
<tr><td rowspan="3">Astra Tech OsseoSpeed™</td><td>3.0</td><td>3.0 mm</td></tr>
<tr><td>3.5/4.0</td><td>3.5/4.0 mm</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i Certain®</td><td>3.25</td><td>3.45 mm</td></tr>
<tr><td>4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i OSSEOTITE®</td><td>3.25</td><td>3.4 mm</td></tr>
<tr><td>3.75, 4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="4">Camlog</td><td>3.3</td><td>3.3 mm</td></tr>
<tr><td>3.8</td><td>3.8 mm</td></tr>
<tr><td>4.3</td><td>4.3 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="4">FRIADENT XiVE®</td><td>3.4</td><td>3.4 mm</td></tr>
<tr><td>3.8</td><td>3.8 mm</td></tr>
<tr><td>4.5</td><td>4.5 mm</td></tr>
<tr><td>5.5</td><td>5.5 mm</td></tr>
<tr><td>MegaGen AnyRidge</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>3.5 mm</td></tr>
<tr><td rowspan="4">NobelActive®,
NobelParallel Conical</td><td>3.0</td><td>3.0 (3.0 mm)</td></tr>
<tr><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3, 5.0</td><td>RP (3.9 mm)</td></tr>
<tr><td>5.5</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="4">NobelReplace® Trilobe</td><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3</td><td>RP (4.3 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.0 mm)</td></tr>
<tr><td>6.0</td><td>6.0 (6.0 mm)</td></tr>
<tr><td rowspan="3">Nobel Brånemark System®</td><td>3.3</td><td>NP (3.5 mm)</td></tr>
<tr><td>3.75, 4.0</td><td>RP (4.1 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="2">Osstem TS</td><td>3.5</td><td>Mini (2.8 mm)</td></tr>
<tr><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular (3.35 mm)</td></tr>
<tr><td rowspan="2">Straumann® Bone Level</td><td>3.3</td><td>NC (3.3 mm)</td></tr>
<tr><td>4.1/4.8</td><td>RC (4.1/4.8 mm)</td></tr>
<tr><td rowspan="3">Straumann® Tissue Level</td><td>3.3</td><td>NNC (3.5 mm)</td></tr>
<tr><td>3.3, 4.1, 4.8</td><td>RN (4.8 mm)</td></tr>
<tr><td>4.8</td><td>WN (6.5 mm)</td></tr>
<tr><td rowspan="3">Zimmer Screw Vent®/
Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1</td><td>3.5 mm</td></tr>
<tr><td>4.7</td><td>4.5 mm</td></tr>
<tr><td>6.0</td><td>5.7 mm</td></tr>
</table></td></tr>
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<table>
<tr><td></td><td></td></tr>
<tr><td>Primary Predicate Devices</td><td></td></tr>
<tr><td>K170588,
DESS Dental Smart Solutions
Terrats Medical SL</td><td>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.

Compatible Implant Systems
<table><tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr><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></table></td></tr>
<tr><td>Reference Devices</td><td></td></tr>
<tr><td>K173908
DESS Dental Smart Solutions
Terrats Medical SL</td><td>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 Aurum™ Abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.
Compatible Implant Systems
<table><tr><th>Implant System Compatibility</th><th>Implant Body</th><th>Implant Platform</th></tr><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></table></td></tr>
<tr><td>K161416
Multi-Unit Abutment Plus
Nobel Biocare AB</td><td>The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.</td></tr>
</table>

Table 3 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	K161416 Multi-Unit Abutment Plus Nobel Biocare AB
Design				
Abutment Designs	Healing, Temporary, Straight, Multi-unit, Locator-type, CAD/CAM Bases, CAD/CAM Blanks,	Healing, Temporary, Straight, Multi-unit, Locator-type, CAD/CAM Bases, CAD/CAM Blanks,	CAD/CAM Bases, CAD/CAM Blanks,	Multi-unit
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Screw-retained
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Multi-unit
Abutment/Implant Platform Diameter, mm	2.52 – 6.0	3.0 – 6.0	3.6 - 5.0	NP, RP, WP
Prosthetic Platform Diameter, mm	4.5-6.5	4.5	4.0 – 6.5	4.8
Multi-unit Abutment Angle	0°, 17°, 30°	Straight (0°)	Straight (0°)	0°, 17°, 30°
All other abutment angles	Straight (0°)	Straight (0°)	Straight (0°)	
Abutment/ Implant Interface	Internal	Internal	Internal	Internal
Material				
Abutments	Ti-6AI-4V ELI Co-Cr-Mo Alloy Zirconia (Y-TZP)	Ti-6AI-4V ELI Zirconia (Y-TZP)	Ti-6AI-4V ELI Co-Cr-Mo Alloy Zirconia (Y-TZP)	Titanium vanadium alloy
Screws	Ti-6AI-4V ELI DLC coating	Ti-6AI-4V ELI DLC coating	Ti-6AI-4V ELI DLC coating	Titanium vanadium alloy