August 14, 2023

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

Re: K231434
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: May 17, 2023
Received: May 17, 2023

Dear Kevin Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K231434

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.

Implant Systems Compatibility

Implant Systems Compatibility	Implant Body Ø, mm	Implant Platform Ø, mm
Internal Hex Connections		
Zimmer 3.1mmD Eztetic™	3.1	2.9
Zimmer Screw-Vent®	3.7	3.5
	4.7	4.5
Zimmer Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
TSX™ Implant System	3.7, 4.1, 4.7	3.5
	5.4, 6.0	4.5
TSX™ Implant System, 3.1mmD	3.1	2.9
External Hex Connections		
Biomet 3i OSSEOTITE® Implants	3.25	3.4
	3.75	4.1
	4.0	4.1

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
K231434
Terrats Medical SL
DESS Dental Smart Solutions

August 7, 2023

ADMINISTRATIVE INFORMATION

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

DEVICE NAME AND CLASSIFICATION

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

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K230143, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K142082, Zimmer 3.1mmD Dental Implant System, Zimmer Dental, Inc.
K013227, Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.
K072589, Tapered Screw-Vent Implant, 4.lmmD, Zimmer Dental, Inc.
K220978, TSX™ Implants, Biomet 3i LLC
K063286, OSSEOTITE® Dental Implants, Implant Innovations, Inc.
K111216, OSSEOTTE® 2 - Dental Implants, Biomet 3i, Inc.
K212538, DESS Dental Implants, Terrats Medical SL

K170588, DESS Dental Implants, Terrats Medical SL
K222269, DESS Dental Implants, Terrats Medical SL
K213063, TLX SRAs and TLX Gold Abutments, Straumann USA, LLC

The reference devices K142082, K013227, K072589, K220978, K063286, K111216 are for OEM implant body clearances. The reference device K212538 is for sterilization, packaging, and shelf life for devices provided sterile to the end user. The reference device K170588 is for compatibility with the Zimmer Screw-Vent®, Zimmer Tapered Screw-Vent®, and Biomet 3i OSSEOTITE® implants. The reference device K222269 is for referenced moist heat sterilization and biocompatibility data. The reference device K213063 is for the technological characteristic of multi-unit abutments provided sterile.

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.

Implant Systems Compatibility

Implant Systems Compatibility	**Implant Body Ø, mm**	**Implant Platform Ø, mm**
Internal Hex Connections		
Zimmer 3.1mmD Eztetic™	3.1	2.9
Zimmer Screw-Vent®	3.7	3.5
	4.7	4.5
Zimmer Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
TSX™ Implant System	3.7, 4.1, 4.7	3.5
	5.4, 6.0	4.5
TSX™ Implant System, 3.1mmD	3.1	2.9
External Hex Connections		
Biomet 3i OSSEOTITE® Implants	3.25	3.4
	3.75	4.1
	4.0	4.1

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the DESS Dental Smart Solutions system, which includes abutments compatible with a variety of original equipment manufacturers (OEM) of dental implants.

This submission adds abutments, designated DESS Multi-Unit Abutments, for implant lines from Zimmer Dental and Biomet 3i (now collectively, ZimVie Dental). The subject device abutments include Multi-Unit Abutments in straight, 17° angled, and 30° angled designs, which are compatible with implants having internal hex or external hex connections. This submission is also to change how previously cleared devices are provided; the change is from previously provided nonsterile to now provided sterile. All abutments are provided with the appropriate abutment screw (if applicable) for attachment to the corresponding implant. The subject device is only intended for multi-unit restorations such as bridges and bars.

A summary of the subject device abutment designs and the compatible OEM implants is provided in the table *Summary of Subject Device Multi-Unit Abutment Designs* on the following page.

Summary of Subject Device Multi-Unit Abutment Designs

Connection and Compatible Implant Line	Subject Device Multi-Unit Abutments				
	Angulation	**Implant-Abutment Platform Ø, mm**	**Gingival Height, mm**	**New Components, Provided Sterile and Nonsterile**	**Previously Cleared Components, Now provided Sterile**
Internal Hex Connections					
Zimmer 3.1mmD Eztetic™ TSX™ Implant System, 3.1mmD	0°	2.9	1, 2, 3, 4, 5	X	
	17°		2.5, 3.5	X	
	30°		3.5, 4.5	X	
Zimmer Screw-Vent® TSX™ Implant System	0°	3.5, 4.5	1, 2, 3, 4, 5	X	X
	17°		2.5, 3.5	X	X
	30°		3.5, 4.5	X	X
Zimmer Tapered Screw-Vent®	0°	3.5, 4.5, 5.7	1, 2, 3, 4, 5	X	X
	17°	3.5, 4.5, 5.7	2.5, 3.5	X	X
	30°	3.5, 4.5, 5.7	3.5, 4.5	X	X
External Hex Connections					
Biomet 3i OSSEOTITE® Implants	17°	3.4	2, 3, 4	X	
	30°	4.1	3, 4, 5	X	

Subject device components that will be provided sterile include:
new (not previously cleared) multi-unit abutments and abutment screw compatible with Zimmer 3.1mmD Eztetic and TSX™ Implant System, 3.1mmD implants; new multi-unit abutments compatible with Screw-Vent®, Tapered Screw-Vent®, and TSX™ implants with implant platform diameters of 4.5 mm and 5.7 mm; new multi-unit abutments compatible with Biomet 3i OSSEOTITE® implants; previously cleared multi-unit abutments compatible with Screw-Vent®, Tapered Screw-Vent®, and TSX™ implants with implant platform diameters of 3.5 mm and 4.5 mm; and previously cleared prosthetic components compatible with all subject device multi-unit abutments.

Subject device components that will be provided non-sterile include:
new (not previously cleared) multi-unit abutments and abutment screw compatible with Zimmer 3.1mmD Eztetic and TSX™ Implant System, 3.1mmD implants; new multi-unit abutments with Screw-Vent®, Tapered Screw-Vent®, and TSX™ implants with implant platform diameters of 4.5 mm and 5.7 mm; and new multi-unit abutments compatible with Biomet 3i OSSEOTITE® implants.

The design dimensions and tolerances of subject device abutments and screws for the Zimmer 3.1mmD Eztetic and TSX™ Implant Systems have been established on the basis of a contractual agreement and working relationship between ZimVie and Terrats Medical SL to ensure that the abutments are designed to fit the corresponding implants. Compatibility of the subject abutments and screws for Screw-Vent®, Tapered Screw-Vent®, and TSX™ implant lines was provided in the prior Terrats Medical SL submission K170588. Compatibility of the subject abutments and screws for the Biomet 3i OSSEOTITE® external hex implants was provided in the prior Terrats Medical SL submission K170588.

Multi-Unit Abutments

The Multi-Unit Abutments are designed for attachment of multi-unit screw-retained restorations and are provided in three (3) designs, straight, angled 17°, and angled 30°. The design of the straight Multi-Unit Abutments is similar to that of straight Multi-Unit Abutments cleared in the primary predicate device K230143 with the exception of the implant connections and platform diameters. The straight Multi-Unit Abutment is provided only in a non-engaging, threaded design that attaches directly to the implant. All straight Multi-Unit Abutments are provided with a prosthetic platform diameter of 4.8 mm. Straight Multi-Unit Abutments are provided only for the compatible internal hex implants listed in the table above. The gingival height of the straight Multi-Unit Abutment ranges from 1 mm to 5 mm in 1 mm increments.

The angled Multi-Unit Abutments are provided in an engaging design that requires an abutment screw, with angulations of 17° and 30°. The angled Multi-Unit Abutments are provided for the compatible internal hex connection implants and the compatible external hex connection implants listed in the table above (on page 3). All angled Multi-Unit Abutments are provided with a prosthetic platform diameter of 4.8 mm, and with gingival heights from 2.5 mm to 4.5 mm. The designs of the angled Multi-Unit Abutments are similar to those of the angled Multi-Unit Abutments cleared in the primary predicate device K230143.All Multi-Unit Abutments, straight and angled, are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

Screws

This submission includes two (2) abutment screws to be used with the subject device abutments: an abutment screw for the compatible internal hex implants with a platform diameter of 2.9 mm; and another abutment screw for all compatible external hex implants (with platforms of 3.4 mm and 4.1 mm). The screws have a hex or hexalobular instrument interface and are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

PERFORMANCE DATA

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

- provided in this submission was non-clinical analysis to evaluate the metallic subject devices and compatible dental implants in the MR environment according to ASTM F2052 (magnetically induced displacement force), ASTM F2213 (magnetically induced torque), ASTM F2182 (RF induced heating), and ASTM F2119 (image artifact), and the FDA guidance document *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021);
- provided in this submission was engineering analysis to demonstrate that the subject device abutments compatible with the Screw-Vent®, Tapered Screw-Vent®, and TSX™ implants do not create a new worst-case construct in terms of mechanical testing according to ISO 14801;
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments compatible with the Zimmer 3.1mmD Eztetic and TSX™ implants, and the performance of the subject device abutments compatible with the Biomet 3i OSSEOTITE® Implants;
- referenced from K222269 was moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2; analysis showed that the subject devices do not create a new worst case for moist heat sterilization;
- referenced from K212538 was gamma irradiation sterilization validation to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to ISO 11137-1 and ISO 11137-2; bacterial endotoxin testing including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 to demonstrate that all sterile product meets a limit of < 20 EU/device; and shelf life testing of samples after accelerated aging equivalent to five (5) years of real time aging according to ASTM F1980, with testing of the packaging sterile barrier and sterility testing of product;
- referenced from K222269 was biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the abutment material ASTM F136; and
- referenced from K170588 was reverse engineering compatibility data for the Zimmer Screw-Vent®, Zimmer Tapered Screw-Vent®, Zimmer TSX™, and Biomet 3i OSSEOTITE® implant lines.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

All abutment screws are similar or identical in design, materials, and technological characteristics to those cleared in the primary predicate device K230143, except for threads and lengths that accommodate the new compatibilities.

Subject device components that are provided non-sterile are to be sterilized by the same moist heat cycle referenced from the primary predicate K230143. The subject devices that are provided non-sterile are packaged in either a PETG blister pack or a PET bag, the same packaging referenced from the primary predicate K230143.

Subject device components that are provided sterile by gamma irradiation are packaged in a PETG blister with a Tyvek® lid. This is the same sterilization, packaging, and 5-year shelf life as validated in the reference device K212538.

The risks associated with use of the subject device angled multi-unit abutments in combination with the compatible implants are mitigated by mechanical testing performed according to ISO 14801.

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

Table of Substantial Equivalence – Indications for Use Statement

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device

K231434

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.

Implant Systems Compatibility
<table>
<tr><th>Implant Systems Compatibility</th><th>Implant Body Ø, mm</th><th>Implant Platform Ø, mm</th></tr>
<tr><td colspan="3">Internal Hex Connections</td></tr>
<tr><td>Zimmer 3.1mmD Eztetic™</td><td>3.1</td><td>2.9</td></tr>
<tr><td rowspan="2">Zimmer Screw-Vent®</td><td>3.7</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td rowspan="3">Zimmer Tapered Screw-Vent®</td><td>3.7, 4.1</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td>6.0</td><td>5.7</td></tr>
<tr><td rowspan="2">TSX™ Implant System</td><td>3.7, 4.1, 4.7</td><td>3.5</td></tr>
<tr><td>5.4, 6.0</td><td>4.5</td></tr>
<tr><td>TSX™ Implant System, 3.1mmD</td><td>3.1</td><td>2.9</td></tr>
<tr><td colspan="3">External Hex Connections</td></tr>
<tr><td rowspan="3">Biomet 3i OSSEOTITE® Implants</td><td>3.25</td><td>3.4</td></tr>
<tr><td>3.75</td><td>4.1</td></tr>
<tr><td>4.0</td><td>4.1</td></tr>
</table>
</td></tr>
<tr><td>Primary Predicate Device

K230143

DESS Dental Smart Solutions

Terrats Medical SL</td><td>
DESS Multi-Unit Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Ø, mm</th><th>Implant Platform Ø, mm</th></tr>
<tr><td>Internal Hex Connection</td><td></td><td></td></tr>
<tr><td rowspan="3">Legacy1</td><td>3.7</td><td>3.5</td></tr>
<tr><td>4.2</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td rowspan="4">Legacy2, simplyLegacy2,
Legacy3, simplyLegacy3,
Legacy4</td><td>3.7</td><td>3.5</td></tr>
<tr><td>4.2</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td>5.2</td><td>4.5</td></tr>
<tr><td>Internal Conical Connection</td><td></td><td></td></tr>
<tr><td rowspan="4">InterActive</td><td>3.2</td><td>3.0</td></tr>
<tr><td>3.7</td><td>3.0</td></tr>
<tr><td>4.3</td><td>3.4</td></tr>
<tr><td>5.0</td><td>3.4</td></tr>
<tr><td rowspan="7">Simply Iconic™</td><td>3.2</td><td>3.0</td></tr>
<tr><td>3.7</td><td>3.0</td></tr>
<tr><td>4.2</td><td>3.0</td></tr>
<tr><td>4.7</td><td>3.0</td></tr>
<tr><td>4.7</td><td>3.4</td></tr>
<tr><td>5.2</td><td>3.4</td></tr>
<tr><td>5.7</td><td>3.4</td></tr>
</table>
</td></tr>
</table>

Table of Substantial Equivalence – Technological Characteristics

	Subject Device	**Primary Predicate Device**	**Reference Device**
	K231434 DESS Dental Smart Solutions Terrats Medical SL	**K230143 DESS Dental Smart Solutions Terrats Medical SL**	**K213063 TLX SRAs and TLX Gold Abutments Straumann USA, LLC**
Reason for Predicate / Reference Device	Not applicable	Designs, materials, manufacturing	Reference for multi-unit abutments provided sterile
Product Codes	NHA	NHA	NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Abutment Designs			
Abutment Types	Multi-Unit	Multi-Unit	Multi-Unit
Prosthesis Attachment	Screw Retained	Screw Retained	Screw Retained
Restoration	Multi-unit	Multi-unit	Multi-unit
Prosthetic Interface Connections	Internal hex, External hex	Internal hex, Internal conical	Internal conical
Abutment/Implant Platform Diameter	2.9 – 5.7 mm	3.0 – 4.5 mm	TLX SRA: 6 mm TLX Gold: 4.0 (NT), 5.0 (RT), and 7.0 (WT)
Prosthetic Platform Diameter	4.8 mm	4.8 mm	TLX SRA: 4.6 mm TLX Gold: *not provided in 510(k) Summary*
Gingival Height	1 mm – 5 mm	1 mm – 5 mm	*Not provided in 510(k) Summary*
Abutment Angulation, degrees	Straight (0°), 17°, 30°	Straight (0°), 17°, 30°	TLX SRA: 17°, 30° TLX Gold: 0°, and up to 30°
Abutment Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	TLX SRA: Ti-6Al-7Nb TLX Gold: Ceramicor®
Abutment Screw Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-7Nb
How Provided			
Sterilization	Non-sterile, and sterile by gamma irradiation	Non-sterile	TLX SRA: Sterile by gamma irradiation TLX Gold: non-sterile
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use