December 10, 2021

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

Re: K212577
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: November 8, 2021
Received: November 9, 2021

Dear Melissa Burbage:

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

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

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

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

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

Sincerely,

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)* K212577

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 Pre-milled 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
NobelActive®, NobelParallel Conical	3.5	NP
	4.3, 5.0	RP
	5.5	WP
Straumann® Bone Level	3.3	NC
	4.1/4.8	RC
Zimmer Screw Vent®/ Tapered Screw-Vent®	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.

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510(k) Summary

Terrats Medical SL

DESS® Dental Smart Solutions
K212577

December 10, 2021

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	Melissa Burbage, BS Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email mburbage@paxmed.com flarson@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	DESS Dental Smart Solutions
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K191986, DESS Dental Smart Solutions, Terrats Medical SL

Additional Predicate Devices
K170588, DESS Dental Smart Solutions, Terrats Medical SL
K173908, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K193425, Pre-Milled Blank, ARUM Dentistry Co. Ltd
K183518, Preat Abutments, Preat Corporation

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 Pre-milled 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
NobelActive®, NobelParallel Conical	3.5	NP
	4.3, 5.0	RP
	5.5	WP
Straumann® Bone Level	3.3	NC
	4.1/4.8	RC
Zimmer Screw-Vent®/ Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to implement a labeling change for certain Pre-milled Blanks of the DESS Dental Smart Solutions abutment system, cleared under K170588, K173908 and K191986, to permit the manufacture of custom abutments with angulation up to 30° and to add three (3) Pre-milled Blanks that also will include such labeling. Design parameters cleared in K170588, K173908 and K191986 were limited to straight abutments only. This change in labeling is for Pre-milled Blanks compatible with three (3) systems: NobelActive/NobelParallel Conical Connection, Straumann Bone Level, and Zimmer Screw-Vent/Tapered Screw-Vent implants. Note that, because NobelActive and Nobel Parallel Conical Connection share the same implant/abutment interface, they are considered one system for purposes of this submission, as they were in K170588, K173908 and K191986. No new compatibilities are added in this submission.

Pre-milled Blanks are designed for fabrication of a custom abutment by a CAD/CAM process. All patient-specific custom abutment fabrication is by prescription on the order of the clinician. Nobel-compatible Pre-milled Blanks are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401*) or from cobalt chromium alloy (Co-Cr-Mo) conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539*. Straumann-compatible and Zimmer-compatible Pre-milled Blanks are made of titanium alloy (Ti-6Al-4V). They are available in engaging designs and are compatible with the implant systems shown the table below *Compatible Implant Systems and Platforms*. Except for the maximum angulation of the final abutment and the addition of three (3) Pre-milled Blanks of 14 mm diameter to the previously cleared Pre-milled Blanks of 10 mm and 14 mm diameter, subject device Pre-milled Blanks are identical to Pre-milled Blanks cleared (with slight variations on the name) in K170588, K173908 and K191986. Compatibility with the implant platform was demonstrated in K170588 and K191986.

The design parameters for the CAD/CAM fabrication of custom abutments from subject device Pre-milled Blanks are:

Minimum wall thickness – 0.45 mm
Minimum post height – 4.0 mm

Maximum gingival height – 6.0 mm
Minimum gingival height – 0.3 mm
Maximum angulation of the final abutment – 30°

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

Compatible Implant Systems and Platforms

Compatible Implant System	DESS Abutment System	Implant Body Diameter, mm	Implant Platform	Connection
NobelActive®, NobelParallel Conical	Active Hex	3.5	NP	Internal
		4.3, 5.0	RP	
		5.5	WP	
Straumann® Bone Level	Conical BL	3.3	NC	Internal
		4.1/4.8	RC	
Zimmer Screw-Vent®/ Tapered Screw-Vent®	Internal Hex USA	3.7, 4.1	3.5	Internal
		4.7	4.5	
		6.0	5.7	

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: static and dynamic testing according to ISO 14801. Information was leveraged from prior clearance (K170588 and K173908) to demonstrate substantial equivalence with regards to sterilization and biocompatibility. 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 additional predicate 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, the additional predicate devices, and the reference devices.

Subject device abutments are substantially equivalent in intended use to the primary predicate device cleared in K191986, the additional predicate devices K170588, K173908 and the reference device K193425. All are intended for use with endosseous dental implants 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 K191986 and additional predicate devices K170588 and K173908.

All subject device abutments are identical in design, materials, and technological characteristics to those of the primary predicate K191986 and additional predicate devices K170588 and K173908. The only change to the subject device is a labeling change to permit custom abutments to be manufactured from the Pre-milled Blanks with an angulation up to 30°, which is substantially equivalent to that of the reference device K193425, and the addition of three new Pre-milled Blanks of 14 mm diameter to the Pre-milled Blanks of 10 mm and 14 mm diameter previously cleared for the predicate devices. No new compatibilities are included in this submission.

Substantial equivalence of the subject device with design parameters that permit angulation of the final abutment is supported by dynamic testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* and by the reference device K183518.

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

CONCLUSION

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

Table of Substantial Equivalence – Indications for Use Statement

Subject Device

DESS Dental Smart Solutions

K212577

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 Pre-milled 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
NobelActive®, NobelParallel Conical	3.5	NP
	4.3, 5.0	RP
	5.5	WP
Straumann® Bone Level	3.3	NC
	4.1/4.8	RC
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

Primary Predicate 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, 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®, NobelReplace/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

Additional Predicate Device

K170588

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 or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

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

Additional Predicate Device

K173908

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 Aurum™ Abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.
Compatible Implant Systems

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

K193425

Pre-Milled Blank
ARUM Dentistry Co. Ltd

ARUM Dentistry's Pre-Milled Blank abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Pre-Milled Blank abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The customized Pre-Milled Blank abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.

ARUM Dentistry's Pre-Milled Blanks are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table

ARUM Pre-Milled Blank		Implant Platform compatibility	Restorative Platform Diameter (mm)	Implant Body diameter (mm)	Abutment Screw
10 mm	14 mm				
CIHE037	CIHE038	NobelActive NP	3.5	3.5	CSTO001
CIHE039	CIHE040	NobelActive NP	3.9	4.3/5.0	CSTO002
CIHE135	CIHE136	NobelActive WP	5.1	5.5	

All digitally-designed Pre-Milled Blank abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.

Reference Device

K183518

Preat Abutments
Preat Corporation

Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant System	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
Astra Tech OsseoSpeed™	3.0	3.0
	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Tapered Internal	3.0	3.0
	3.5	3.5
	4.0	4.5
HIOSSEN ET III	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Implant Direct Legacy	3.2	3.0
	3.7, 4.2	3.5
	4.7, 5.2	4.5
	5.7, 7.0	5.7
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1
NobelActive®	3.5	NP
	4.3, 5.0	RP
Nobel Replace™	3.5	NP
	4.0, 4.3, 5.0	RP
	5.0	WP
	6.0	6.0
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN
	4.8, 6.5	WN
Zimmer Screw-Vent®/Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Additional Predicate Devices		Reference Devices	
	K212577 DESS Dental Smart Solutions Terrats Medical SL	K191986 DESS Dental Smart Solutions Terrats Medical SL	K170588 DESS Dental Smart Solutions Terrats Medical SL	K173908 DESS Dental Smart Solutions Terrats Medical SL	K193425 Pre-Milled Blank ARUM Dentistry Co. Ltd	K183518 Preat Abutments Preat Corporation
Reason for Predicate	n/a	Design	Design	Design	30° angle	Performance Testing
Design						
Abutment Designs	CAD/CAM Blanks	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	CAD/CAM Blanks	Healing, Temporary, Straight, Multi-unit, CAD/CAM Bases, CAD/CAM Blanks
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained	Cement-retained Screw-retained
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment/Implant Platform Diameter, mm	2.52 – 6.0	2.52 – 6.0	3.0 – 6.0	3.6 - 5.0	3.5 – 5.5	3.0 – 6.5
Prosthetic Platform Diameter, mm	4.5 – 6.5	4.5-6.5	4.5	4.0 – 6.5	3.5 – 5.1	3.0 – 6.5
Blank Abutment Angulation	0° to 30°	0°	0°	0°	0° to 30°	0° to 30°
Abutment/ Implant Interface	Internal	Internal	Internal	Internal	Internal	Internal
Material	Ti-6AI-4V ELI Co-Cr-Mo Alloy	Ti-6AI-4V ELI Co-Cr-Mo Alloy	Ti-6AI-4V ELI	Ti-6AI-4V ELI Co-Cr-Mo Alloy	Ti-6AI-4V ELI	Ti-6AI-4V alloy