April 13, 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: K230143
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: January 17, 2023
Received: January 18, 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)* K230143

Device Name

DESS Dental Smart Solutions

Indications for Use (Describe)

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

Compatible Implant Systems	Implant Body Ø, mm	Implant Platform Ø, mm
Internal Hex Connection		
Legacy1	3.7	3.5
	4.2	3.5
	4.7	4.5
Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, Legacy4	3.7	3.5
	4.2	3.5
	4.7	4.5
	5.2	4.5
Internal Conical Connection		
InterActive	3.2	3.0
	3.7	3.0
	4.3	3.4
	5.0	3.4
Simply Iconic™	3.2	3.0
	3.7	3.0
	4.2	3.0
	4.7	3.0
	4.7	3.4
	5.2	3.4
	5.7	3.4

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
K231043
Terrats Medical SL
DESS® Dental Smart Solutions

February 27, 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
K222269, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K061319, Spectra Dental Implant System, Implant Direct, LLC
K192221, Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts, Implant Direct Sybron Manufacturing, LLC
K130572, InterActive / SwishPlus 2 Implant System, Implant Direct Sybron Manufacturing LLC
K201553, Simply Iconic™ Implants, Implant Direct Sybron Manufacturing LLC

INDICATIONS FOR USE STATEMENT

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

Compatible Implant Systems	Implant Body Ø, mm	Implant Platform Ø, mm
Internal Hex Connection		
Legacy1	3.7	3.5
	4.2	3.5
	4.7	4.5
Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, Legacy4	3.7	3.5
	4.2	3.5
	4.7	4.5
	5.2	4.5
Internal Conical Connection		
InterActive	3.2	3.0
	3.7	3.0
	4.3	3.4
	5.0	3.4
Simply Iconic™	3.2	3.0
	3.7	3.0
	4.2	3.0
	4.7	3.0
	4.7	3.4
	5.2	3.4
	5.7	3.4

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the DESS Dental Smart Solutions system, which includes abutments cleared previously in K170588, K173908, K191986, K203464, K212577, K212628, K222269, and K222288. These previously cleared abutments are compatible with a variety of original equipment manufacturers (OEM) of dental implants. This submission adds abutments for implant lines from Implant Direct Sybron Manufacturing LLC (hereinafter, Implant Direct). The subject device abutments are compatible with various Implant Direct internal hex and internal conical implant bodies. The subject device abutments include Multi-Unit Abutments in straight, 17° angled, and 30° angled designs. All abutments are provided with the appropriate abutment screw (if applicable) for attachment to the corresponding implant. All abutments and screws are provided non-sterile. 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

Connections	Subject Device Multi-Unit Abutments	Implant-Abutment Platform Ø, mm	Gingival Height, mm	Compatible Implant Direct Implant Lines
Internal hex	Straight	3.5	1 – 5	Legacy1 Legacy2 simplyLegacy2 Legacy3 simplyLegacy3 Legacy4
		4.5	1 – 3	
	17° Angled	3.5	2.5, 3.5	
		4.5	2.5, 3.5	
	30° Angled	3.5	3.5, 4.5	
		4.5	3.5, 4.5	
Internal conical	Straight	3.0	1.5 – 3.5	InterActive Simply Iconic™
		3.4	1.5 – 4.5	
	17° Angled	3.0	2.5, 3.5	
		3.4	2.5, 3.5	
	30° Angled	3.0	3.5, 4.5	
		3.4	3.5, 4.5	

The design dimensions and tolerances of subject device abutments and screws have been established on the basis of a contractual agreement and working relationship between Implant Direct and Terrats Medical SL to ensure that the abutments are designed to fit the corresponding Implant Direct implants listed above.

Multi Unit Abutments

The Multi-Unit Abutment is designed for attachment of multi-unit screw-retained restorations and is 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 K222269 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 for Implant Direct internal hex implants with 3.5 mm and 4.5 mm platform diameters, and for Implant Direct internal conical implants with 3.0 mm and 3.4 mm platform diameters. The gingival height of the straight Multi-Unit Abutment ranges from 1.5 mm to 5.5 mm.

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 same Implant Direct implants as the straight Multi-Unit Abutments (internal hex implants with 3.5 mm and 4.5 mm platform diameters, and internal conical implants with 3.0 mm and 3.4 mm platform diameters). 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 K222269. All Multi-Unit Abutments are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

Screws

This submission includes three (3) abutment screws to be used with the subject device abutments. 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, referenced, or relied upon to demonstrate substantial equivalence included:

sterilization validation according to ISO 17665-1 and ISO 17665-2, referenced from K222269;

biocompatibility according to ISO 10993-5 and ISO 10993-12, referenced from K222269;

non-clinical analysis performed to evaluate the metallic subject devices and compatible dental implants in the MR environment using scientific rationale and published literature (TO Woods, JG Delfino, and S Rajan, *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation*, Volume 49, No. 2, 2021, pp. 783-795); the analysis addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021) including magnetically induced displacement force and torque; and

static compression and compression fatigue testing of worst-case constructs comprising the subject device Multi Unit Angled Abutments and compatible OEM implants in conformance with ISO 14801.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device abutments are substantially equivalent in intended use to the primary predicate device K222269. 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 K222269, except for the list of compatible OEM implants. An additional difference between the IFUS of the subject device and that of the primary predicate K222269 is the language in K222269 describing the requirement of a validated milling center for CAD-CAM abutments. This language is not applicable to the subject device abutments. All reference devices identified are for OEM implant body compatibilities.

The range of dimensions of the subject device abutments, including the abutment-implant platform diameter, prosthetic platform diameter, gingival height, and abutment angulation, is encompassed by the corresponding multi-unit abutments in the primary predicate device K222269.

All subject device components are provided non-sterile and are to be sterilized by the same moist heat cycle recommended in the primary predicate K222269. The subject devices are packaged in either a PETG blister pack or a PET bag, the same packaging as cleared in K222269.

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

K231043

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>
<tr><td>Primary Predicate Device

K222269

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 DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.
Compatible Implant Systems
<table>
<tr><th>Compatible Implant System
(Connection)</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td rowspan="3">PRIMA CONNEX
(Internal TiLobe, Tapered & Straight)</td><td>3.3, 3.5</td><td>3.5</td></tr>
<tr><td>4.0, 4.1</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td rowspan="3">GENESIS
(Internal TiLobe)</td><td>3.5, 3.8</td><td>3.5/3.8</td></tr>
<tr><td>4.5</td><td>4.5</td></tr>
<tr><td>5.5, 6.5</td><td>5.5/6.5</td></tr>
<tr><td rowspan="3">MOLARIS TILOBEMAXX
(Internal TiLobe)</td><td>7</td><td>5.7</td></tr>
<tr><td>8</td><td>6.5</td></tr>
<tr><td>9</td><td>7.5</td></tr>
<tr><td rowspan="3">MOLARIS I-HEXMRT
(Internal Hex)</td><td>7</td><td>5.7</td></tr>
<tr><td>8</td><td>6.5</td></tr>
<tr><td>9</td><td>7.5</td></tr>
<tr><td rowspan="2">PALTOP ADVANCED CLASSIC
(Internal Hex)</td><td>3.25</td><td>NP (3.25)</td></tr>
<tr><td>3.75, 4.2, 5.0</td><td>SP (3.75/4.2/5.0)</td></tr>
<tr><td rowspan="3">PALTOP ADVANCED PLUS
(Internal Hex)</td><td>3.0, 3.25</td><td>NP (3.25)</td></tr>
<tr><td>3.75, 4.2, 5.0</td><td>SP (3.75/4.2/5.0)</td></tr>
<tr><td>6.0</td><td>WP (6.0)</td></tr>
</table></td></tr>
</table>

	PALTOP DYNAMIC (Internal Hex)	3.0, 3.25	NP (3.25)
		3.75, 4.2, 5.0	SP (3.75/4.2/5.0)
		6.0	WP (6.0)
	PALTOP DYNAMIC CONICAL (Internal Conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)

Table of Substantial Equivalence – Technological Characteristics

	Subject Device	**Primary Predicate Device**
	K231043 DESS Dental Smart Solutions Terrats Medical SL	**K222269 DESS Dental Smart Solutions Terrats Medical SL**
Reason for Predicate Device	Not applicable	Abutment designs, materials, sterilization
Product Codes	NHA	NHA
Intended Use	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, Straight (0°), 17°, 30°	Multi-Unit, Straight (0°), 17°, 30° Ti Base AURUM Base Premilled Blank
Prosthesis Attachment	Screw Retained	Cement-retained Screw Retained
Restoration	Multi-unit	Single-unit Multi-unit
Prosthetic Interface Connections	Internal	Internal
Abutment/Implant Platform Diameter	3.0 – 4.5 mm	MUAs: 3.25 mm – 7.5 mm
Prosthetic Platform Diameter	4.8 mm	MUAs: 4.8 mm, 6.0 mm
Gingival Height	1 mm – 5 mm	MUAs: 1 mm – 5 mm
Abutment Angulation, degrees	Straight (0°), 17°, 30°	MUAs: Straight (0°), 17°, 30°
Abutment Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Abutment Screw Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
How Provided		
Sterilization	Non-sterile	Non-sterile
Usage – All Components	Single patient, single use	Single patient, single use