DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Terrats Medical SL
% Linda Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

August 8, 2017

Re: K170588
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: June 6, 2017
Received: July 7, 2017

Dear Linda Schulz:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170588

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 TiBase or Pre-milled Blank 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

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.

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

K170588
August 8, 2017

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Avenida La Ferrería (Pol Ind La Ferrería) 62 Montcada i Reixac, 08110 Spain Telephone +34 93 564 60 06 Fax +34 93 564 73 17
Official Contact	Roger Terrats, COO
Representative/Consultant	Linda Schulz, BSDH, RDH 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: LSchulz@paxmed.com KThomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	DESS Dental Smart Solutions
Common Name	Dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate
K120414, OsseoSpeed™ Plus, Astra Tech AB

Reference Predicates
K072878, Modification to: Locator Implant Anchor, Zest Anchors, Inc.
K092341, Low Profile Abutment, Biomet 3i
K150203, Medentika CAD/CAM Abutments, Medentika GmbH
K150367, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

Compatible Implant System Predicates

K063341	3i OSSEOTITE Certain® Dental Implants	Implant Innovations, Inc.
K063286	OSSEOTITE® Dental Implants	Implant Innovations, Inc.
K101732	OsseoSpeed™	Astra Tech AB
K073075	FRIADENT Implant Systems	DENTSPLY International, Inc.
K142260	NobelActive®	Nobel Biocare AB
K073142	NobelReplace Hexagonal Implants	Nobel Biocare AB
K050705	TiUnite® Implants	Nobel Biocare AB
K050406	NOBELSPEEDY™ Implants	Nobel Biocare USA LLC
K022562	Various Brånemark System Implants – Immediate Function Indication	Nobel Biocare AB
K140878	Straumann® Bone Level Tapered Implants	Straumann USA, LLC
K062129	P.004 Implants	Institut Straumann AG
K130222	Straumann® Dental Implant System SLActive and Roxolid Product Families	Straumann USA, LLC
K112160	Tapered Screw-Vent® X Implant	Zimmer Dental, Incorporated

INDICATIONS FOR USE

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

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

DEVICE DESCRIPTION

DESS Dental Smart Solutions is a dental implant abutment system that includes seven abutment design types (Healing, Temporary, Straight, TiBase, Pre-milled Blank, DESS LOC, Multi-Unit), and ten abutment connections compatible with eleven implant systems. Platform diameters range from 3.3 mm to 5.7 mm. Corresponding implant body diameters range from 3.25 mm to 6.0 mm. The following table outlines the body and platform diameters by abutment design and corresponding implant line.

Summary of Abutment Designs

DESS Abutment System	Healing	Temporary Non-Engaging	Temporary Engaging	Straight	Ti Base Non-Engaging	Ti Base Engaging	Pre-milled Blank Engaging	DESS LOC	Multi-Unit	OEM Implant System
Internal Hex "Click"	NP 3.4 RP 4.1 WP 5.0	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP		3i Certain® 3.4 (NP), 4.1 (RP), 5.0 (WP)
External Hex USA	NP 3.4 RP 4.1 WP 5.0	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP	NP RP	3i OSSEOTITE® 3.4 (NP), 4.1(RP), 5.0 (WP)
Internal Hex Conic	RP 3.5/4.0 WP 4.5/5.0	RP WP	RP WP	RP WP	RP WP	RP WP	RP WP		RP WP	OsseoSpeedTM 3.5/4.0 (RP), 4.5/5.0 (WP)
Internal Hex FD	NP 3.4 RP 3.8 WP 4.5	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP		NP RP WP		FRIADENT XiVE® 3.4 (NP), 3.8 (RP), 4.5 (WP)
Active Hex	NP 3.5 RP 3.9	NP RP	NP RP	NP RP	NP RP	NP RP	NP RP	NP RP	NP RP	NobelActive® NP (3.5), RP (3.9) NobelReplace® Conical NP (3.5), RP (3.9)
Tri-Lobe	NP 3.5 RP 4.3 WP 5.0	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP	NP RP WP	NobelReplace® Trilobe NP (3.5), RP (4.3), WP (5.0)
External Hex Universal	NP 3.5 RP 4.1 WP 5.1	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	RP WP	NP RP	NP RP WP	Brånemark System® NP (3.5), RP (4.1), WP (5.1)
Conical BL	NC 3.3 RC 4.1	NC RC	NC RC	NC RC	NC RC	NC RC	NC RC	NC RC	NC RC	Straumann® Bone Level NC (3.3), RC (4.1)
Octagon	RN 4.8 WN 6.5	RN WN	RN WN	RN	RN WN	RN WN	RN WN	RN	RN WN	Straumann® Tissue Level RN (4.8), WN (6.5)
Internal Hex USA	NP 3.4 RP 4.5 WP 5.7	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP WP	NP RP	NP RP	Tapered Screw-Vent 3.4 (NP), 4.5 (RP), 5.7 (WP)

Abutments are offered in a variety of connection types to enable compatibility with a large number of currently marketed implants. Straight, Temporary and TiBase abutments have a SelectGrip® surface. DESS LOC Abutments have a ZrN coating. Selected DESS screws include DLC coating. DESS Dental Smart Solutions abutments are straight abutments. All abutments are provided non-sterile.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation to an SAL of 10^{-6} according to ISO 17665-1 and ISO 17665-2 to ensure sterilization of the final finished device; biological evaluation according to ISO 10993-1 and cytotoxicity testing according to ISO 10993-5 for all surfaces to demonstrate that all devices are non-cytotoxic; SEM evaluation and measurement of the ZrN and SelectGrip surfaces to demonstrate suitability of the surface; and engineering and dimensional analysis of OEM implant bodies, OEM abutments, and OEM abutment fixation screws to confirm compatibility.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the predicate devices shown above. Below are summary tables comparing the Indications for Use and the technological characteristics of the subject device and the predicate devices.

Comparison of Indications for Use Statements

<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 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>
</table>

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Primary Predicate Device</td><td></td></tr>
<tr><td>K120414
OsseoSpeed™ Plus
Astra Tech AB</td><td>Implants:
The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:
• replacing single and multiple missing teeth in the mandible and maxilla,
• immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
• especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective,
• immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm, or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.
The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors.
Abutments:
Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.
Atlantis Abutments:
The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous; patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.
The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous; implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous; patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.</td></tr>
<tr><td>Reference Predicate Devices</td><td></td></tr>
<tr><td>K072878
Modification to:
Locator Implant Anchor
Zest Anchors, Inc.</td><td>Not available</td></tr>
<tr><td>K092341
Low Profile Abutment
Biomet 3i, Inc.</td><td>Biomet 3i Low Profile Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained to the abutment.</td></tr>
<tr><td>K150203
Medentika CAD/CAM Abutments
Medentika GmbH</td><td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>
Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td></tr>
<tr><td>K150367
Neodent Implant System
JJGC Indústria e Comércio de Materiais Dentários SA</td><td>Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations.
PreFace Abutment is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. PreFace Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.</td></tr>
</table>

Comparison of Technological Characteristics

	Subject Device	**Primary Predicate**	**Reference Predicates**			
		K120414	K072878	K092341	K150203	K150367
	DESS Dental Smart Solutions	OsseoSpeed™ Plus	Modification to: Locator Implant Anchor	Low Profile Abutment	Medentika CAD/CAM Abutments	Neodent Implant System
	Terrats Medical SL	Astra Tech AB	Zest Anchors, Inc.	Biomet 3i, Inc.	Medentika GmbH	JJGC Indústria e Comércio de Materiais Dentários SA
Design						
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Overdenture attachment	Screw-retained	Cement-retained	Cement-retained Screw-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Overdenture	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Abutment Platform Diameter (mm)	3.4 – 5.7	3.0 – 5.4	2.5 – 6.5	3.4 – 5.0	3.0 – 7.0	3.0 – 6.0
Abutment Angle	Straight	Straight to 30°	Straight	Straight to 30°	Straight to 30°	Straight to 30°
Abutment/Implant Interface	Internal, External	Internal	Internal, External	Internal, External	Internal, External	Internal
Material						
Abutment	Ti-6Al-4V	Ti-6Al-4V Zirconia, Gold, PEEK	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
Screw	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V

DESS Dental Smart Solutions abutments are substantially equivalent in design, function, material, size, and Indications for Use to OsseoSpeed Plus (K120414) and Medentika CAD/CAM Abutments (K150203). All are intended for use with endosseous dental implants in the maxilla and mandible to provide prosthetic support. Digital files for DESS Dental Smart Solutions abutments and for Medentika CAD/CAM Abutments are to be sent to a validated milling center for manufacture. Differences in the type of restoration named or specific milling center stated in the Indications for Use statement do not affect the intended use.

Subject device abutment designs and function are substantially equivalent to design and function of abutments included in K120414, K072878, K092341, K150203 and K150367. Implant/abutment interface compatibility for the subject device is substantially equivalent to the compatible implant system predicates listed above.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and design of the abutments. The subject and predicate devices 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.