December 14, 2021

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

Re: K212538
Trade/Device Name: DESS Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: November 9, 2021
Received: November 10, 2021

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
Assistant Director
DHT1B: Division of Dental andENT 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)*

K212538

Device Name

DESS Dental Implants

Indications for Use *(Describe)*

DESS® dental implants are indicated for surgical placement in the upper or lower jaw in edentulous or partially edentulous patients for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. They are designed to support single or multi-unit restorations in splinted or non-splinted applications, as well as to support overdenture attachment systems. DESS® dental implants may be used for immediate or early implantation following extraction or loss of natural teeth, and may be used for immediate or delayed loading techniques. Implants may be loaded immediately when good primary stability is achieved and occlusal loading is appropriate. Implants of diameter 3.0 mm, 3.3 mm and 3.5 mm are indicated for use in reduced interdental spaces, where there is not enough alveolar bone for a larger diameter implant. The use of 3.0 mm, 3.3 mm and 3.5 mm diameter implants is intended only for rehabilitation of the anterior region of the mouth.

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 Implants

December 13, 2021

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	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 flarson@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	DESS® Dental Implants
Common Name	Dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K142260, NobelActive®, Nobel Biocare AB

Additional Predicate Devices
K140878, Straumann® Bone Level Tapered Implants Titanium SLA, Straumann USA, LLC
K171784, Straumann® Dental Implant System, Straumann USA, LLC
K212125, Nobel Biocare Dental Implant Systems Portfolio - MR Conditional. Nobel Biocare AG
K023113, Replace TiUnite Endosseous Implant, Nobel Biocare USA Inc.

INDICATIONS FOR USE STATEMENT

DESS® dental implants are indicated for surgical placement in the upper or lower jaw in edentulous or partially edentulous patients for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. They are designed to support single or multi-unit restorations in splinted or non-splinted applications, as well as to support overdenture attachment systems. DESS® dental implants may be used for immediate or early implantation following extraction or loss of natural teeth and may be used for immediate or delayed loading techniques. Implants may be loaded immediately when good primary stability is achieved and occlusal loading is appropriate. Implants of diameter 3.0 mm, 3.3 mm and 3.5 mm are indicated for use in reduced interdental spaces, where there is not enough alveolar bone for a larger diameter implant. The use of 3.0 mm, 3.3 mm and 3.5 mm diameter implants is intended only for rehabilitation of the anterior region of the mouth.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for two designs of DESS Dental Implants. The implants are compatible with DESS Dental Smart Solutions abutments manufactured by the sponsor of this submission, Terrats Medical SL and cleared under K170588, K173908 and K191986. The new dental implants are parallel-walled root-form threaded endosseous dental implants made from unalloyed titanium, ranging in diameter from 3.0 mm to 5.5 mm and in length from 7 mm to 18 mm, as described more fully below.

This submission includes two designs of DESS Dental Implants, designated Active and Bone Level. The external portion of each design is threaded, with a uniform major diameter and a slightly decreasing minor diameter along the length of the implant. The apical portion of each is tapered and includes cutting flutes to facilitate the insertion of the implant into the alveolar bone. Both designs have an internal conical connection, an internal anti-rotation feature (used for engaging abutment designs) that also serves to facilitate insertion into bone, and an internal screw channel to secure an abutment. Differences between the designs include the type of anti-rotational feature which, in the Active implant is an internal hex and in the Bone Level implant is an internal 4-lobed design. The external thread of the Active implant ends below the crest of the implant and a machined collar with shallow grooves is located between the end of the external thread and the crest of the implant. The external thread of the Bone Level implant ends below the crest of the implant, and the collar is included in the surface treatment. The endosseous surface of each implant is treated with a grit blasting and acid etching process to provide a rough surface for attachment of bone.

The subject device dental implants are summarized in the following table.

Implant Line	Body Ø, mm	Platform Name	Lengths, mm										
Active	3.0	3.0				10	11.5		13		15		
	3.5	NP			8.5	10	11.5		13		15		18
	4.3	RP			8.5	10	11.5		13		15		18
	5.0	RP			8.5	10	11.5		13		15		18
	5.5	WP	7		8.5	10	11.5		13		15		
Bone Level	3.3	NC		8		10		12		14		16	18
	4.1	RC		8		10		12		14		16	18
	4.8	RC		8		10		12		14		16	18

All subject device implants are made of unalloyed titanium conforming to ISO 5832-2 *Implants for surgery – Metallic materials – Part 2: Unalloyed titanium*.

The subject device dental implants are compatible with abutments and prosthetic components cleared previously in K170588, K173908 and K191986.

PERFORMANCE DATA

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

- gamma irradiation sterilization validation to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25}, according to ISO 11137-1 and ISO 11137-2;
- bacterial endotoxin testing including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 on all batches of finished devices to demonstrate that all sterile product meets a limit of $\leq$ 20 EU/device;
- cytotoxicity testing (MEM elution), performed on the final finished subject device according to ISO 10993-5 and ISO 10993-12;
- shelf life testing, including 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;
- surface characterization, including determination of surface roughness by measuring microscopic surface area according to ISO 25178 *Geometrical product specifications (GPS) — Surface texture: Areal* and analysis of surface chemistry by XPS (X-ray Photoelectron Spectroscopy);
- static and dynamic testing performed according to ISO 14801. All test constructs included the DESS dental implant with the smallest body diameter that is compatible with a DESS Angled Multi Unit Abutment, the corresponding compatible DESS Angled Multi Unit Abutment 30° 4.5 mm RP, the abutment screw, the prosthetic coping (interface CoCr) and the prosthetic screw.

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 predicate device and the additional predicate devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the additional predicate devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate device K142260 and additional predicate devices. The differences between the IFUS for the subject device and that of the primary predicate implant (K142260) include the omission in the latter of reference to edentulous or partially edentulous patients. However, the primary predicate IFUS includes no exclusion for either edentulous or partially edentulous patients and the additional predicates include the same explicit statement as the subject device. Likewise, the

IFUS for K142260 includes no mention of immediate or early placement. However, the IFUS for the additional predicates include such a statement.

A difference between the IFUS for the subject device and those for the Straumann additional predicates K140878 and K171784 is that the latter include no special limitations for small diameter implants, while the subject device IFUS includes limitations on the use of diameter 3.0 mm, 3.3 mm and 3.5 mm. These limitations for the subject device are similar to those for the primary predicate K142260. Slight differences in the language of the IFUS do not affect the intended use as an endosseous dental implant for support of abutments and a prosthesis to restore chewing function.

All subject device DESS Dental Implants are similar in design to the predicate implants listed above. DESS Active implants are similar in design, including thread form, dimensions and anti-rotational features to those of NobelActive implants cleared in K142260. The machined collar of the DESS Active implant is similar to those of the additional predicate devices K212125 and K023113. DESS Bone Level implants are similar in design to Straumann Bone Level implants cleared in K140878 and K171784. The ranges of implant diameters, platform diameters and lengths are the same as or within the range of those of the predicate devices.

All subject device implants components are provided sterile by gamma irradiation, the same sterilization method used in K170588, K173908 and K191986.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of identical 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 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 **K212538** **DESS Dental Implants** **Terrats Medical SL**	DESS® dental implants are indicated for surgical placement in the upper or lower jaw in edentulous or partially edentulous patients to restore patient esthetics and chewing function. They are designed to support single or multi-unit restorations in splinted or non-splinted applications, as well as to retain overdentures. DESS® dental implants may be used for immediate or early implantation following extraction or loss of natural teeth and may be used for immediate or delayed loading techniques. Implants may be loaded immediately when good primary stability is achieved and occlusal loading is appropriate. Implants of diameter 3.0 mm, 3.3 mm and 3.5 mm are indicated for use in reduced interdental spaces, where there is not enough alveolar bone for a larger diameter implant. The use of 3.0 mm, 3.3 mm and 3.5 mm diameter implants is intended only for rehabilitation of the anterior region of the mouth..
Primary Predicate Device **K142260** **NobelActive®** **Nobel Biocare AB**	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.
Additional Predicate Device **K140878** **Straumann® Bone Level Tapered Implants Titanium SLA** **Straumann USA, LLC**	Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).
Additional Predicate Device **K171784** **Straumann® Dental Implant System** **Straumann USA, LLC**	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Additional Predicate Devices			
	K212538 **DESS Dental Implants** **Terrats Medical SL**	**K142260** **NobelActive®** **Nobel Biocare AB**	**K140878** **Straumann® Bone Level Tapered Implants Titanium SLA** **Straumann USA, LLC**	**K171784** **Straumann® Dental Implant System** **Straumann USA, LLC**	**K212125** **Nobel Biocare Dental Implant Systems Portfolio - MR Conditional** (Brånemark Implant) **Nobel Biocare AG**	**K023113** **Replace TiUnite Endosseous Implant** **Nobel Biocare USA**
Design						
Implant Design	Root-form, threaded	Root-form, threaded	Root-form, threaded	Root-form, threaded	Root-form, threaded	Root-form, threaded
Placement	Bone-level	Bone-level	Bone-level	Bone-level	Bone-level	Bone-level
Implant diameters, mm	3.0, 3.3, 3.5, 4.1, 4.3, 4.8, 5.0, 5.5	3.0, 3.5, 4.3, 5.0, 5.5	3.3, 4.1, 4.8	3.3, 4.1, 4.8	4.0, 5.0	3.5, 4.3, 5.0, 6.0
Implant lengths, mm	7, 8, 8.5, 10, 11.5, 12, 13, 14, 15, 16, 18	7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0	8, 10, 12, 14, 16	8, 10, 12, 14	7, 8.5, 10, 11.5, 13, 15, 18	8, 10, 11.5, 13, 16
Abutment/Implant Platform Diameter, mm	2.5, 2.75, 3.0, 3.3, 4.4	2.5, 3.0, 3.3, 4.4	2.75 (NC), 3.3 (RC)	2.75 (NC), 3.3 (RC)	4.1, 5.1	3.5, 4.3, 5.0, 6.0
Machined collar, mm	0.77, 0.92, 0.97, 1.36	Not stated - Anodized	NA	NA	0.8, 0.2 (Brånemark Mk III TiUnite)	0.75 (Replace Select Tapered), 1.5 (Replace Select Tapered PMC)
Connection Type	Internal conical with hex (Active) Internal conical with anti-rotation (Bone Level)	Internal (conical with) hex	CrossFit® (Internal conical with anti-rotation)	CrossFit® (Internal conical with anti-rotation)	External Hex (Brånemark)	Internal Tri-channel
Material	Titanium Grade 4	Titanium Grade 4	Titanium Grade 4 or TiZr alloy	Titanium Grade 4 or TiZr alloy	Titanium Grade 4	Titanium Grade 4
Surface	SLA	TiUnite	SLA or SLActive	SLA or SLActive	TiUnite or fully machined	TiUnite