510(k) Summary

Terrats Medical SL DESS® Dental Smart Solutions K212577

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ADMINISTRATIVE INFORMATION

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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 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 System	Implant Body Diameter, mm	Implant Platform
N-1-14-4:® N-1-1D11-1	3.5	NP
NobelActive®, NobelParallel	4.3, 5.0	RP
Conical	5.5	WP
Straumann® Bone Level	3.3	NC
Straumann Bone Level	4.1/4.8	RC
7:	3.7, 4.1	3.5
Zimmer Screw-Vent®/ Tapered Screw-Vent®	4.7	4.5
Screw-vent	6.0	5.7

Compatible Implant Systems

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 Premilled 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®,		3.5	NP	
NobelParallel Conical	Active Hex	4.3, 5.0	RP	Internal
NobelParallel Conical		5.5	WP	
Straumann® Bone	Conical BL	3.3	NC	Internal
Level	Collical BL	4.1/4.8	RC	Internal
Zimmer Screw-Vent®/		3.7, 4.1	3.5	
Tapered Screw-Vent®	Internal Hex USA	4.7	4.5	Internal
Tapered Screw-Vent		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	3.5	NP
Conical	4.3, 5.0	RP
Conicar	5.5	WP
Straumann® Bone Level	3.3	NC
Straumann Bone Level	4.1/4.8	RC
7:	3.7, 4.1	3.5
Zimmer Screw Vent®/ Tapered Screw-Vent®	4.7	4.5
Sciew-vent	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
	3.6	2.9 mm
Astra Tech EV	4.2	3.5 mm
	4.8	4.1 mm
	3.0	3.0 mm
Astra Tech OsseoSpeed TM	3.5/4.0	3.5/4.0 mm
	4.5/5.0	4.5/5.0 mm
	3.25	3.45 mm
Biomet 3i Certain®	4.0	4.1 mm
	5.0	5.0 mm
	3.25	3.4 mm
Biomet 3i OSSEOTITE®	3.75, 4.0	4.1 mm
	5.0	5.0 mm
	3.3	3.3 mm
Camlog	3.8	3.8 mm
Caminog	4.3	4.3 mm
	5.0	5.0 mm
	3.4	3.4 mm
FRIADENT XiVE®	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
	3.0	3.0 (3.0 mm)
NobelActive®,	3.5	NP (3.5 mm)
NobelReplace/NobelParallel Conical	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
<u> </u>	3.5	NP (3.5 mm)
NobelReplace® Trilobe	4.3	RP (4.3 mm)
Trobencepiace Thobe	5.0	WP (5.0 mm)
	6.0	6.0 (6.0 mm)
_	3.3	NP (3.5 mm)
Nobel Brånemark System®	3.75, 4.0	RP (4.1 mm)
	5.0	WP (5.1 mm)
Osstem TS	3.5	Mini (2.8 mm)
Obstein 15	4.0, 4.5, 5.0, 6.0, 7.0	Regular (3.35 mm)
Straumann® Bone Level	3.3	NC (3.3 mm)
Stradinaini Bone Ecvei	4.1/4.8	RC (4.1/4.8 mm)
	3.3	NNC (3.5 mm)
Straumann® Tissue Level	3.3, 4.1, 4.8	RN (4.8 mm)
	4.8	WN (6.5 mm)
Zimmer Screw Vent®/ Tapered Screw-	3.3, 3.7, 4.1	3.5 mm
Vent®	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 TM	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 AurumTM 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 TM	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

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ARUM Pre-Milled Blank		Implant Platform compatibility	Restorative Platform	Implant Body diameter (mm)	Abutment Screw		
10 mm	14 mm	Diamet	Diameter (mm)	(mm) diameter (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	CS10002		

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)	
	3.25	3.4	
2: OGGEOTITE® G ®	4.0	4.1	
3i OSSEOTITE® Certain®	5.0	5.0	
	6.0	6.0	
	3.0	3.0	
Astra Tech OsseoSpeed TM	3.5, 4.0	3.5/4.0	
•	4.5, 5.0	4.5/5.0	
	3.0	3.0	
BioHorizons Tapered Internal	3.5	3.5	
•	4.0	4.5	
HIOGGEN ET HI	3.5	Mini	
HIOSSEN ET III	4.0, 4.5, 5.0, 6.0, 7.0	Regular	
	3.2	3.0	
Invalent Direct I access	3.7, 4.2	3.5	
Implant Direct Legacy	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	
NobelActive	4.3, 5.0	RP	
	3.5	NP	
N 1 1 D 1 TM	4.0, 4.3, 5.0	RP	
Nobel Replace™	5.0	WP	
	6.0	6.0	
Straumann® Bone Level	3.3	NC	
Straumann® Bone Level	4.1, 4.8	RC	
Straumann® Tissue Level	3.3, 4.1, 4.8	RN	
Straumann 11ssue Level	4.8, 6.5	WN	
	3.3, 3.7, 4.1	3.5	
Zimmer Screw-Vent®/Tapered Screw-Vent®	4.7	4.5	
-	6.0	5.7	

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Additional Predicate Devices		Referen	ce 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