March 9, 2023

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

Re: K221301
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, PNP
Dated: February 8, 2023
Received: February 8, 2023

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 -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K221301

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 DESS Bases or Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	3.5, 4.5, 5.5
Astra Tech EV	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons Internal	3.0, 3.4, 3.8	3.0
	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Camlog	3.3	3.3
	3.8	3.8
	4.3	4.3
	5.0	5.0
Friadent XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
	5.5	5.5
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace/ NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
NobelReplace® Trilobe	3.5	NP
	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem TS	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Straumann® BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3	NNC
	3.3, 4.1, 4.8	RN
	4.8	WN

Zimmer Screw-Vent® / Tapered Screw-Vent®	3.3, 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

March 9, 2023

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda 75-99 Barberà del Vallès 08210 Barcelona, Spain Telephone: +34 935 646 006 Fax: +34 935 647 317
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Representative/Consultant	Melissa Burbage 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: mburbage@paxmed.com; 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, PNP
Classification Panel	Dental Products Panel
Reviewing Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K222288, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K201860, Elos Accurate® Hybrid Base™, Elos Medtech Pinol A/S
K180703, VITA YZ ST and VITA YZ XT, VITA Zahnfabrik H.Rauter GmbH. Co.
K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG
K151455, 3Shape Abutment Designer Software, 3Shape A/S

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 DESS Bases or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	3.5, 4.5, 5.5
Astra Tech EV	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons Internal	3.0, 3.4, 3.8	3.0
	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Camlog	3.3	3.3
	3.8	3.8
	4.3	4.3
	5.0	5.0
Friadent XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
	5.5	5.5
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace/ NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
NobelReplace® Trilobe	3.5	NP
	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem TS	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Straumann® BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3	NNC
	3.3, 4.1, 4.8	RN
	4.8	WN
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions abutment system cleared under K222288 to add the ability for the subject device Base Abutments and Pre-milled (Blank) Abutments to be manufactured via a digital dentistry workflow by using scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. There are no changes to the abutment design or implant compatibilities, however, there is a new material for the zirconia superstructure. All part numbers have been cleared within previous submissions for manufacturing at a validated milling center. The purpose of this submission is to allow manufacturing via digital dentistry workflow and to add a new zirconia material for the superstructures of the two-piece abutment.

The subject device DESS Dental Smart Solutions abutments provide a range of prosthetic solutions for dental implant restoration. DESS abutments are offered in a variety of connection types to enable compatibility with currently marketed dental implants. All abutments are provided non-sterile, and each abutment is supplied with the appropriate abutment screw (if applicable) for attachment to the corresponding implant.

Subject device Base Abutments are designed for fabrication of a patient-specific CAD/CAM zirconia superstructure on which a crown may be placed. They are two-piece abutments for which the second part (or top half) is the ceramic superstructure. They also may be used for support of a crown directly on the abutment.

All patient-specific custom abutment fabrication for Base Abutments and Pre-milled (Blank) Abutments is by prescription on the order of the clinician. The subject device Pre-milled (Blank) Abutments and all zirconia superstructures for use with the subject device Ti Base Interface, DESS Aurum Base, ELLIPTIBase, and DESS C-Base will be manufactured using a digital dentistry workflow by using scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

The digital dentistry workflow uses scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The digital workflow includes the following products (not subject devices of this submission):

- Ceramic material: VITA YZ ST and VITA YZ XT (K180703)
- Cement: Ivoclar Vivadent Multilink Hybrid Abutment Cement (K130436)
- Intraoral Scanner: 3Shape TRIOS A/S Series Intraoral Scanner (510(k) exempt under 21 CFR 872.3661)
- Desktop scanner: 3Shape D900 Dental Lab Scanner (510(k) exempt under 21 CFR 872.3661)
- Abutment design software: 3Shape Abutment Designer Software (K151455)
- Milling machine: VHF R5 by vhf camfacture AG with DentalCAM and DentalCNC 7 software

The design parameters for the CAD/CAM zirconia superstructure to be used on Base Abutments:

Minimum wall thickness – 0.4 mm
Minimum post height for single-unit loading
Ti Base Interface – 4.2 mm
DESS Aurum Base – 4.0 mm
ELLIPTIBase – 4.0 mm
C-Base – 4.7 mm
CoCr Base – 4.5 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

The design parameters for the CAD/CAM Pre-Milled Blank custom abutments:

Minimum wall thickness – 0.4 mm
Minimum post height – 4.0 mm
Maximum gingival height – 6.0 mm
Minimum gingival height – 0.3 mm
All Pre-Milled Blank are for straight abutments only.

For the CAD/CAM Pre-milled Blanks that are compatible with Astra Tech EV (except for 3.0 mm implants), Astra Tech OsseoSpeed, Biomet 3i Certain, Nobel Active/NobelParallel Conical (except for 3.0 mm implants), NobelReplace Trilobe, Nobel Brånemark, Straumann Bone Level, and Zimmer Screw-Vent/Tapered Screw-Vent, the following design parameters may be used:

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°

Screws

DESS Dental Smart Solutions screws are designed to attach the abutment to the implant or the prosthesis to the abutment. The screws were cleared in K170588, K173908, K191986, K203464, K212577, and K212628. There have been no changes to the screws and there are no new subject device screws. Screws are available with and without a DLC (Diamond-like Carbon) coating.

Summary of Subject Device Components and Implant Platforms for Compatible Implant Systems

Compatible Implant Systems	DESS Abutment System	Ti Base Interface, Engaging	Ti Base Interface, Non-engaging	DESS Aurum Base, Engaging	DESS Aurum Base, Non-engaging	ELLIPTIBase, Engaging	DESS C-Base	CoCr Base	Pre-milled Blank Ti, Engaging	Screws
Ankylos C/X	Internal Ank	3.5, 4.5, 5.5	3.5, 4.5, 5.5				3.5, 4.5, 5.5	3.5, 4.5, 5.5	3.5, 4.5, 5.5	X
Astra Tech EV	Conic EVO	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4	3.6, 4.2, 4.8	3.6, 4.2, 4.8	3.0	3.6, 4.2, 4.8	3.6, 4.2, 4.8	3.0, 3.6, 4.2, 4.8, 5.4	X
Astra Tech OsseoSpeed	Internal Hex Conic	3.0, 3.5/4.0, 4.5/5.0	3.0, 3.5/4.0, 4.5/5.0	3.5/4.0, 4.5/5.0	3.5/4.0, 4.5/5.0		3.5/4.0, 4.5/5.0		3.0, 3.5/4.0, 4.5/5.0	X
BioHorizons Internal	BH Internal	3.0, 3.5, 4.5, 5.7	3.0, 3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.0		3.0, 3.5, 4.5, 5.7	3.5, 4.5, 5.7	X
Biomet 3i Certain	Internal Hex Click	3.4, 4.1, 5.0	3.4, 4.1, 5.0	3.4, 4.1, 5.0	3.4, 4.1, 5.0		3.4, 4.1, 5.0	3.4, 4.1, 5.0	3.4, 4.1, 5.0	X
Biomet 3i OSSEOTITE	External Hex USA	3.4, 4.1, 5.0	3.4, 4.1, 5.0	3.4, 4.1, 5.0	3.4, 4.1, 5.0		3.4, 4.1, 5.0		3.4, 4.1, 5.0	X
Camlog	Internal CAM	3.3, 3.8, 4.3, 5.0	3.3, 3.8, 4.3, 5.0	3.8, 4.3	3.8, 4.3			3.8, 4.3	3.3, 3.8, 4.3, 5.0	X
Frident XiVE	Internal Hex FD	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5	3.4, 3.8, 4.5		3.4, 3.8, 4.5, 5.5	3.8, 4.5, 5.5	3.8, 4.5, 5.5	X
Neodent Grand Morse	Neo GM	Grand Morse	Grand Morse	Grand Morse	Grand Morse				Grand Morse	X
NobelActive, NobelParallel Conical	Active Hex	3.0, NP, RP, WP	3.0, NP, RP, WP	NP, RP	NP, RP	3.0	NP, RP, WP	NP, RP	3.0, NP, RP, WP	X
NobelReplace Trilobe	Tri-lobe	NP, RP, WP, 6.0	NP, RP, WP, 6.0	NP, RP, WP	NP, RP, WP		NP, RP, WP, 6.0		NP, RP, WP, 6.0	X
Nobel Brånemark System	External Hex Universal	NP, RP, WP	NP, RP, WP	NP, RP	NP, RP		NP, RP		NP, RP, WP	X
Osstem TS	Conic OSS	Mini, Regular	Mini, Regular	Mini, Regular	Mini, Regular		Mini, Regular		Mini, Regular	X
Straumann BLX	Conical BLX	RB/WB, WB	RB/WB, WB	RB/WB, WB	RB/WB, WB				RB/WB, WB	X
Straumann Bone Level	Conical BL	NC, RC	NC, RC	NC, RC	NC, RC	NC	NC, RC	NC, RC	NC, RC	X
Straumann Tissue Level	Octagon	NNC, RN, WN	NNC, RN, WN	RN, WN	RN, WN	NNC	RN, WN	RN, WN	NNC, RN, WN	X
Zimmer Screw Vent / Tapered Screw Vent	Internal Hex USA	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5, 4.5, 5.7	X

MATERIAL COMPOSITION

All subject device abutments and screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401*) or from Co-Cr-Mo alloy conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*. These materials are the same as those used for devices cleared in K222288.

The new material recommended for zirconia superstructures on Ti Base Interface, DESS Aurum Base and ELLIPTIBase, C-Base, and CoCr Base is VITA YZ ST and VITA YZ XT, conforming to ISO 6872 *Dentistry – Ceramic Materials* and cleared in K180703. This material is equivalent to those cleared in K222288.

The cement recommended in labeling for bonding of superstructures is Multilink Hybrid Abutment Cement from Ivoclar Vivadent AG, cleared under K130436. This material is the same as that used for devices cleared in K222288.

All subject device components are manufactured from the same or similar materials, are treated with the same surface treatments (SelectGrip® surface, DLC coating and anodization), and are manufactured in the same or similar facilities using the same manufacturing processes cleared in K170588, K173908, K191986, K203464, K212577, and K212628. The facilities may be different in that the CAD/CAM portion of the abutment may be manufactured in dental laboratories; however, the equipment and procedures are intended to be the same as those used by the validated milling centers.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included the following: Sterilization validation according to ISO 17665-1, ISO 17665-2 and ISO 14937; biocompatibility testing according to ISO 10993-5 and ISO 10993-12 for titanium; fatigue testing and reverse engineering analysis of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility; and MR Conditional labeling were leveraged from K222288. Biocompatibility testing according to ISO 10993-5 and ISO 10993-12 was included for the new zirconia material used for zirconia superstructures, tested alone and cemented to Ti Base abutments and for patient-specific abutments fabricated from Pre-milled Blanks using the new manufacturing (point of care) process. Software verification included testing of restrictions that prevent design of components outside of the stated design parameters. In addition, the abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified by the user. To address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the abutment blanks, validation testing of the CAM restriction zones was conducted, including verification to show avoidance of damage or modifications of the connection geometry, and locking of restriction zones from user editing in the CAM software. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

Subject device abutments are substantially equivalent in intended use to the primary predicate device K222288 and reference devices K201860, K180703, K130436, and K151455. 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 device K222288 for compatible OEM implants and manufacturing using a validated milling center.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the reference device K201860 for manufacturing using a digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories. The differences between the subject device IFUS and primary predicate device K222288 do not raise different questions of substantial equivalence, as demonstrated by manufacturing software validation and workflow validation.

All subject device abutments (base and blanks) and screws are equivalent in design, materials and technological characteristics to those of the primary predicate device K222288. There are no changes to the abutment designs or implant compatibilities. However, there is a new Y-TZP material for the zirconia superstructure. All part numbers have been cleared within previous submissions for manufacturing via a validated milling center. The purpose of this submission is to allow manufacturing via digital dentistry workflow.

CONCLUSION

The subject device, the primary predicate device, the additional predicate devices, and reference device have the same intended use, have similar technological characteristics, and are made of the same or similar materials. The subject device, the primary predicate device and reference devices encompass the same range of physical dimensions, manufactured by similar methods, 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.

Device Comparison Table

Comparison	Subject Device	Predicate Devices	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K222288 DESS Dental Smart Solutions Terrats Medical SL	K201860 Elos Accurate® Hybrid Base™ Elos Medtech Pinol A/S
Product Code	NHA, PNP	NHA	NHA, PNP
Reason for predicate/reference	n/a	Abutment design and OEM compatibility	Digital dentistry workflow
Intended Use	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function
Indications	DESS Dental Smart Solutions abutments are intended for dental prosthetic restorations. DESS Dental Smart Solutions abutments are used as an interface between a dental implant or dental abutment and a dental restoration and will be attached to the implant or abutment using a prosthetic screw and attached to the dental restoration by cementing. All digitally designed custom abutments for use with Base abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories. *For complete Indications for Use statement on OEM Compatibility see Section 4.*	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. *For complete Indications for Use statement on OEM Compatibility see 510(k) Summaries for K170588, K173908, K191986, K203464, K212577, K212628 in Section 12.*	The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Hybrid Base™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using a prosthetic screw and attached to the zirconia superstructure by cementing. The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in Table 1: The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. *For complete Indications for Use statement on OEM Compatibility see 510(k) Summary for K151789 in Section 12.*
Design			
Abutment Designs	CAD/CAM Bases, CAD/CAM Blanks	Healing, Temporary, Straight, Multi-unit, Locator-type, CAD/CAM Bases, CAD/CAM Blanks	CAD/CAM Bases
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Screw Retained Abutment Cement Retrained Superstructure
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment/Implant Platform Ø, mm	2.52 – 6.5	2.52 – 6.5	3.0 – 6.0
Abutment Angle	30° max* for Blanks 0° for TiBases	30° max* for Blanks 30° max* for TiBases	20° max for TiBases
Material			
Abutment Material (Blanks)	Ti-6AI-4V ELI	Ti-6AI-4V ELI Co-Cr-Mo Alloy	n/a

Comparison	Subject Device	Predicate Devices	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K222288 DESS Dental Smart Solutions Terrats Medical SL	K201860 Elos Accurate® Hybrid Base™ Elos Medtech Pinol A/S
Abutment Material (Bases)	Ti-6AI-4V ELI Co-Cr-Mo Alloy	Ti-6AI-4V ELI Co-Cr-Mo Alloy	Ti-6AI-4V alloy
Screw Material	Ti-6AI-4V ELI DLC coating	Ti-6AI-4V ELI DLC coating	Ti-6AI-4V alloy DLC coating
Superstructure Material (Bases)	Zirconium Oxide (Y-TZP), K180703	Zirconium Oxide (Y-TZP)	Zirconium Oxide (Y-TZP)
Surface	Anodization and a SelectGrip® surface	Anodization and a SelectGrip® surface	Anodized, non-anodized, Medicarb/DLC coating on screw
Workflow			
Manufacturing	Digital Dentistry Workflow & Validated Milling Center	Validated Milling Center	Digital Dentistry Workflow
Digital Design Workflow	3Shape Intraoral scanner Trios series, 3Shape E-series and D/R2000 Lab Scanner, 3Shape Abutment Designer Software (3Shape A/S) K151455	Terrats approved milling facility	3Shape Intraoral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) K151455
Digital Manufacturing Workflow	VHF R5 By vhf camfacture AG with DentalCAM & DentalCNC	Terrats approved milling facility	CORiTEC Milling Unit (Imes-Icore)

*30° for select OEM Connections as listed above in the Subject Device Description. 0° for all other compatible connections.