Terrats Medical SL
% Melissa Burbage
Principal Regulatory Consultant
Enerxen Consulting, Inc.
1155 Metcalfe Street
Suite 1572
Montreal, Quebec H3B2V6
CANADA

October 31, 2025

Re: K251547
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: May 20, 2025
Received: October 1, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K251547

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.

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	3.6	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	3.8	3.8
	4.3	4.3
Friadent XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
Implant Direct Legacy	3.2	3.0
	3.7	3.7
	4.2	4.2
	4.7	4.7
	5.2	5.2
Keystone Prima Connex	3.3, 3.5	3.5
	4.0, 4.1	4.1
	5.0	5.0
Keystone Genesis	3.5, 3.8	3.5/3.8
	4.5	4.5
	5.5, 6.5	5.5/6.5
Keystone Molaris	7	5.7
	8	6.5
	9	7.5
Keystone Paltop	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)	6.0 WP (6.0)
Keystone Paltop Dynamic Conical	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
MIS C1	3.30	NP
	3.75, 4.20	SP
MIS Seven	3.3	NP (3.1)
	3.75, 4.2	SP (3.5)
	5.0, 6.0	WP (4.5)
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 (3.5)
	4.3, 5.0	RP (3.9)
	5.5	WP (5.1)
NobelReplace® Trilobe	3.5	NP (3.5)
	4.3	RP (4.3)
	5.0	WP
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem TS / Hiossen	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, 4.1, 4.8	RN
Zimmer Eztetic	3.1	2.9
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
Zimmer Spline	3.25	3.25
	3.75, 4.0	3.75/4.0
	5.0	5.0
Zimmer SwissPlus	3.7	3.8
	4.8	4.8

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
K251547

October 30, 2025

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	Class II
Primary Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Division	DHT1B: Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K170588, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K191986, DESS Dental Smart Solutions, Terrats Medical SL
K212628, DESS Dental Smart Solutions, Terrats Medical SL
K222288, DESS Dental Smart Solutions, Terrats Medical SL
K240208, DESS Dental Smart Solutions, Terrats Medical SL
K242340, DESS Dental Smart Solutions, Terrats Medical SL
K083324, LOCATOR® Implant Anchor Attachment System, Zest Anchors, Incorporated

Reference Devices for OEM implant body clearances
K111287, Astra Tech Implant System Plus, Astra Tech AB
K120414, OsseoSpeed™ Plus, Astra Tech AB

K101732, Astra Tech Implant System, Astra Tech AB
K042429, BioHorizons The Prodigy System™ Endosseous Implants, BioHorizons Implant Systems, Inc.
K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implant Systems, Inc.
K063286, OSSEOTITE Dental Implants, Implant Innovations, Inc.
K192221, Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3, Implant Direct Sybron Manufacturing, LLC
K051614, PrimaConnex Internal Connection, Lifecore Biomedical (Keystone)
K201334, Keystone Dental XL Dental Implant System, Keystone Dental, Inc.
K072768, Restore®, Stage-1®, Renova®, PrimaSolo®, and PrimaConnex® Dental Implants, Lifecore Biomedical, Inc.
K101545, Genesis Implant System, Keystone Dental, Inc.
K112795, Paltop Dental Implant System, Paltop Advanced Dental Solutions Ltd.
K210117, Paltop Narrow Implant, Paltop Advanced Dental Solutions, Ltd.
K220200, Paltop Conical Implant System, Paltop Advanced Dental Solutions, Ltd.
K110955, AnyRidge Internal Implant System, Megagen Co., Ltd.
K172505, MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection, MIS Implants Technologies Ltd
K180282, MIS Internal Hex Dental Implant System, MIS Implants Technologies Ltd

K142260, NobelActive®, Nobel Biocare AB
K102436, NobelActive® 3.0, Nobel Biocare AB
K173418, NobelParallel™ Conical Connection, 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
K161604, OSSTEM Implant System, OSSTEM Implant Co., Ltd.
K173961, Straumann® BLX Implant System, Institut Straumann AG

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.

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	3.6	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	3.8	3.8
	4.3	4.3
Friadent XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
Implant Direct Legacy	3.2	3.0
	3.7	3.7
	4.2	4.2
	4.7	4.7
	5.2	5.2
Keystone Prima Connex	3.3, 3.5	3.5
	4.0, 4.1	4.1
	5.0	5.0
Keystone Genesis	3.5, 3.8	3.5/3.8
	4.5	4.5
	5.5, 6.5	5.5/6.5
Keystone Molaris	7	5.7
	8	6.5
	9	7.5
Keystone Paltop	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)	6.0 WP (6.0)
Keystone Paltop Dynamic Conical	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
MIS C1	3.30	NP
	3.75, 4.20	SP
MIS Seven	3.3	NP (3.1)
	3.75, 4.2	SP (3.5)
	5.0, 6.0	WP (4.5)
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 (3.5)
	4.3, 5.0	RP (3.9)
	5.5	WP (5.1)
NobelReplace® Trilobe	3.5	NP (3.5)
	4.3	RP (4.3)
	5.0	WP

Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem TS / Hiossen	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, 4.1, 4.8	RN
Zimmer Eztetic	3.1	2.9
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
Zimmer Spline	3.25	3.25
	3.75, 4.0	3.75/4.0
	5.0	5.0
Zimmer SwissPlus	3.7	3.8
	4.8	4.8

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions for the DESSLoc Attachment system cleared under K170588, K191986, K212628, K222288, K240208, and K242340 and to:

- include OEM platform compatibilities to the DESSLoc Abutment design that have been previously cleared in other DESS Abutment designs,
- include new OEM platform compatibility for MIS C1 Dental Implant System,
- include attachment components (retention inserts and housing) including reprocessing information in labeling.

The DESSLoc Attachment System consists of abutments and device-specific accessories (retention inserts and denture housings) for resilient attachment of prostheses to endosseous dental implants. There have been no changes to the design of the DESSLoc abutments, the design is the same that has been cleared in the above submissions. The abutments are made of titanium alloy and coated with zirconium nitride (ZrN). The nylon retention insert is manufactured from Polynil® (polyamide 6.6) or Vestamid® Care ML GB30 (polyamide 12). The denture housing is made of titanium alloy with a machined surface or anodized surface. The DESSLoc abutment is compatible with OEM implants, as listed below.

Table 1 Summary of OEM Compatibilities for DESSLoc Attachment System

Compatible Implant Lines	DESS Abutment System Name	Implant-Abutment Platform Ø, mm	Gingival Height, mm
Ankylos C/X	Internal Ank	2.52	2, 3, 4
Astra Tech EV	Conic EVO	2.9, 3.5, 4.1, 5.4	1, 2, 3, 4, 5, 6
Astra Tech OsseoSpeed™	Internal Hex Conic	3.0	1, 2, 3, 4
		3.5/4.0	1, 2, 3, 4, 5
		4.5/5.0	1, 2, 3, 4, 5
BioHorizons Internal	Internal Hex BH	3.5, 4.5, 5.7	1, 2, 3, 4, 5, 6
Biomet 3i Certain®	Internal Hex “Click”	3.4, 4.1, 5.0	0.5, 1, 2, 3, 4, 5, 6
Biomet 3i OSSEOTITE®	External Hex USA	3.4	0.5, 1, 2, 3, 4, 5, 6
		4.1	1, 2, 3, 4, 5, 6
		5.0	0.5, 1, 2, 3, 4, 5, 6
Camlog	Internal CAM	3.8, 4.3	1, 2, 3, 4
FRIADENT (Dentsuply) XiVE®	Internal Hex FD	3.4, 3.8, 4.5	1, 2, 3, 4

Compatible Implant Lines	DESS Abutment System Name	Implant-Abutment Platform Ø, mm	Gingival Height, mm
Implant Direct Legacy	Legacy	3.0	1, 2, 3, 4, 5, 6
		3.5, 4.5	0.5, 1, 2, 3, 4, 5, 6
		5.7	1, 2, 3, 4, 5, 6
Keystone Prima Connex	Internal Tilobe	3.5, 3.5/3.8 4.1, 4.5, 5.0, 5.5/6.5, 5.7, 6.5, 7.5	0.5, 1, 2, 3, 4, 5, 6
Keystone Paltop	Internal Hex	3.0, 3.25, 3.75, 4.2, 5.0, 6.0, 6.5, 7.5	1, 2, 3, 4, 5, 6
Keystone Paltop Dynamic Conical	Internal Conical	3.25, 3.75, 4.2, 5.0	1, 2, 3, 4, 5, 6
MegaGen AnyRidge	Conic Anyr	3.5	1, 2, 3, 4, 5, 6
MIS C1	MIS C1 Internal	2.75, 3.15	1, 2, 3, 4, 5, 6
MIS Seven	Internal Hex MI	3.1 NP	0.5, 1, 2, 3, 4, 5, 6
		3.65 SP	1, 2, 3, 4, 5, 6
		4.5 WP	1, 2, 3, 4, 5, 6
Neodent Grand Morse	Neo GM	Grand Morse (GM)	1, 2, 3, 4, 5, 6
NobelActive®, NobelParallel Conical	Active Hex	3.0, NP (3.5), RP (4.3)	1, 2, 3, 4, 5, 6
NobelReplace ® Trilobe	Tilobe	NP (3.5), RP (4.3), WP (5.0)	1, 2, 3, 4, 5, 6
Nobel Brånemark System®	External Hex Universal	NP (3.5)	1, 2, 3, 4, 5, 6
		RP (4.1)	0.5, 1, 2, 3, 4, 5, 6
		WP (5.1)	1, 2, 3, 4, 5
Osstem TS / Hiossen	Conic OSS	Mini, Regular	1, 2, 3, 4, 5, 6
Straumann BLX	Conical BLX	RB/WB	1, 2, 3, 4, 5, 6
Straumann® Bone Level	Conical BL	NC (3.3)	2, 3, 4, 5, 6
		RC (4.1)	1, 2, 3, 4, 5, 6
Straumann® Tissue Level	Octagon	RN (4.8)	1, 2, 3, 4, 5
Zimmer Eztetic™	Internal EZ	2.9	1, 2, 3, 4, 5, 6
Zimmer Screw Vent®/ Tapered Screw-Vent	Internal Hex USA	3.5, 4.5, 5.7	0.5, 1, 2, 3, 4, 5, 6
Zimmer Spline	External SPL	3.25	1, 2, 3, 4, 5, 6
		4.0	1, 2, 3, 4, 5, 6, 7, 8
		5.0	1, 2, 3, 4, 5, 6
Zimmer Swiss Plus	Internal Swiss	3.8, 4.8	1, 2, 3, 4, 5, 6

MATERIAL COMPOSITION

All abutments and metal denture housing are manufactured from titanium alloy conforming to the requirements of ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*.

The nylon retention insert is manufactured from Polynil® (polyamide 6.6) or Vestamid® Care ML GB30 (polyamide 12).

PERFORMANCE DATA

Non-clinical testing data submitted to demonstrate substantial equivalence included:

- Sterilization validation according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO 17665-2 *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1* for the subject device abutments,

housing, and Vestamid® retention inserts.

- Disinfection validation according to ISO 15883-5 *Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy* and AAMI TIR30 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices* for the Polynil® inserts.
- Biocompatibility testing according to ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* and ISO 10993-10 *Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization* for both types of inserts
- Non-clinical worst-case MRI review to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the subject device components and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.
- Retention testing of each different type of retention insert in a denture housing to measure removal force from an abutment over multiple sets of insertion/removal cycles compared to the predicate device
- Strength and fatigue testing of the Vestamid retention inserts following steam sterilization.
- Reverse engineering analysis of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility for new OEM connections.
- In addition, the labeling for the device has been revised to include instructions on high level disinfection for the Polynil retention inserts, prior to use in a patient, using an FDA cleared disinfectant.

EQUIVALENCE TO MARKETED DEVICES

Table 2 Table of Substantial Equivalence

Comparison	Subject Device	Predicate Devices	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K170588 DESS Dental Smart Solutions Terrats Medical SL	K083324 LOCATOR Implant Anchor Attachment System Zest Anchors, Inc..
Product Code	NHA	NHA	NHA
Reason for predicate/reference	n/a	abutment design	retention insert and housing
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 to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.	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.	The LOCATOR Implant Anchor Abutment for Endosseous Dental Implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.
Design			
Abutment Diameter, mm	2.9 – 5.7	2.9 – 5.7	3.25 – 6.5
Gingival Height, mm	1 – 6	0 – 6	0 – 8
Abutment Angulation	Straight	Straight	Straight
Abutment/Implant Interface	Internal Thread	Internal Thread	Internal Thread, Conical, External Hex, Internal Hex, Internal Multi Lobe
Restoration type	Overdenture	Overdenture	Overdenture
Prosthesis Attachment Type	Nylon Insert retained in Denture Attachment Housing	Nylon Insert retained in Denture Attachment Housing	Nylon Insert retained in Denture Attachment Housing
Reprocessing of the Abutment	End user steam sterilization	End user steam sterilization	End user steam sterilization
Material			
Abutment	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Abutment Coronal Surface Coating	Zirconium Nitride (ZrN)	Zirconium Nitride (ZrN)	Titanium Nitride (TiN)
Prosthetic Retention Component	Polynil® (polyamide 6.6) or Vestamid®	Polynil®	Nylon
Reprocessing of Insert	Polynil: disinfectant Vestamid: end user steam sterilization	Not included	Not included

Subject device abutments are similar to the predicate device K170588, K191986, K212628, K222288, K240208, and K242340. Both are intended for use with endosseous dental implants to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. The indications are similar with the added compatibility of the Implant Direct Legacy Dental Implants, Keystone Dental Implants, MIS C1 Dental Implants, MIS Seven Dental Implants, OSSTEM TS/Hiossen Dental Implants, and Straumann BLX Dental Implants. These additional OEM compatibilities have been cleared with other DESS abutments in K212628, K240208, and K230143 or have completed reverse engineering.

The subject device consists of abutments, retention inserts, and denture housings for attachment of prostheses to endosseous implants similar to predicate devices. The subject device is similar in its indication for use, sizes, shapes, and surface coating. It is identical to the predicate devices in coronal geometry such that the mechanism for overdenture retention is the same. The diameters offered are same to those of the predicate devices and are dependent on the implant compatibility. The gingival heights offered are same to those of the predicate devices.

All DESSLOC abutments have the same coronal ridge retention design that attaches to the overdenture component by an interference (snap) fit similar to that of the predicate device. Retention inserts are fixed within a metal denture housing which is embedded in an overdenture prosthesis. The retention inserts allow for varying levels of retention similar to the additional predicate device K083324. This connection allows the denture to be retained on the abutments while the majority of loading is supported by the contact of the denture with the gingival tissue surrounding the mandibular and maxillary ridges. In this submission, the specific retention inserts have been identified and included in the submission for clearance as NHA devices.

The subject device abutments are manufactured from the same material, titanium alloy, and have a surface coating that are applied above the implant/abutment interface. The zirconium nitride (ZrN) coating is identical to the predicate devices with a thickness of approximately 2 and 3 μm. As with the primary predicate device, the coating is non-porous, the surface roughness of the machined abutment surface is maintained, and the coating is not applied to enhance tissue attachment to the device.

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 the same materials. The subject device, the primary predicate, and 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.