January 14, 2025

Zest Anchors, LLC
Maleata Hall
Director Regulatory Affairs
2875 Loker Ave E
Carlsbad, California 92010

Re: K243272
Trade/Device Name: LOCATOR Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 15, 2024
Received: October 16, 2024

Dear Maleata Hall:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243272

Device Name
LOCATOR Angled Abutment

Indications for Use *(Describe)*
The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable restorations retained by endosseous implants to restore masticatory function for the patient.

IMPLANT COMPATIBILITY

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
LAA 15°, Straumann, BLX	Straumann	3.5, 3.75, 4.0, 4.5	BLX	Regular Base	2.9	Bone Level
		5.0, 5.5, 6.5	BLX	Wide Base	2.9	Bone Level
LAA 15°, Nobel (NP)	Nobel	3.5	NobelActive, NobelParallel CC, NobelReplace CC	Narrow Platform	3.0	Conical
LAA 15°, Nobel (RP)		4.3	NobelActive, NobelParallel CC, NobelReplace CC	Regular Platform	3.5	Conical
LAA 15°, Neodent (GM)	Neodent	3.5, 3.75, 4.0, 5.0, 6.0	Helix GM	N/A	3.0	Conical / Grand Morse
		3.5, 4.3, 5.0	Drive GM	N/A		Conical / Grand Morse
		3.5, 3.75, 4.0, 5.0	Titamax GM	N/A		Conical / Grand Morse
LAA 15°, TSV	ZimVie	3.7 & 4.1 Green	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	3.5	Internal Hex
		4.7 Purple	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	4.5	Internal Hex

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary – K243272
LOCATOR Angled Abutment

i. General Information on Submitter

Applicant: Zest Anchors, LLC
Address: 2875 Loker Avenue East
Carlsbad, CA 92010 USA
Telephone: (800) 262-2310
Contact Person: David Lin
Contact Title: Sr. Regulatory Affairs Specialist
Email: regulatoryaffairs@zestdent.com
Date Prepared: December 16, 2024

ii. General Information on Device

Proprietary Name: **LOCATOR Angled Abutment**
Common Name: Dental Implant Abutment
Regulation Number: 21 CFR 872.3630
Classification Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA (Abutment, Implant, Dental, Endosseous)

iii. Predicate Device

Predicate Device	**510(k) Number**
LOCATOR Angled Abutment: Zest Anchors, LLC	K233587
Reference Devices	**510(k) Number**
Hex-Lock Prepared Abutment (Straight & Angled), Zimmer Dental Inc.	K052600
SBF 15 Esthetic Abutment 1mm NP, Model 33699, SFB 15 Esthetic Abutment 1mm RP, Model 33701, CFB 15 Esthetic Abutment 2mm, Nobel Biocare AB	K062749
Neodent® Implant System – GM Line, JJGC Industria e Comercio de Materiais Dentarios SA	K163194
Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.	K013227
Tapered Screw-Vent Implant, 4.1mm, Zimmer Dental, Inc.	K072589
NobelActive Internal Connection Implant, Nobel Biocare AB	K071370

iv. Description of Device

The purpose of this submission is to expand the LOCATOR Angled Abutment product line by adding new devices, specifically abutments compatible with various dental implant systems from different dental implant manufacturers (OEMs). The Locator Angled Abutment (K233587) has been cleared by the FDA for compatibility with the Straumann BLX implant. This 510(k) submission expands compatibility to include the Zimmer TSV 3.5/4.5(ZimVie), Nobel RP/NP, and Neodent Grand Morse (GM) implant systems. The LOCATOR Angled Abutment is designed and cleared to be used with LOCATOR FIXED (K213391) and LOCATOR Attachment Systems (K072878) for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants in the mandible or maxilla.

The LOCATOR Angled Abutment consists of various height abutments with identical attachment features compared to LOCATOR Abutments of the LOCATOR Implant Attachment System, cleared in K072878. The LOCATOR Angled Abutment will be used with the accessories of the LOCATOR Implant Attachment System (retention inserts, denture attachment housing, and ancillary processing parts) and LOCATOR FIXED Attachment System (fixed inserts, denture attachment housing) for the attachment of a restoration. The LOCATOR Angled Abutment interfacing features are provided at a 15 degree angle to allow for angle correction, substantially equivalent to the predicate device of K233587. The LOCATOR Angled Abutments are manufactured from titanium (Ti-6Al-4V) and are titanium nitride (TiN) coated, identical to the predicate device.

The abutment/implant interface of the LOCATOR Angled Abutment cleared in K233587 is compatible with the OEM implant system, Straumann BLX. The submission herein is to expand the abutment/implant interface compatibility of the LOCATOR Angled Abutment to include the Zimmer (ZimVie) TSV 3.5/4.5, Nobel RP/NP, and Neodent Grand Morse implant systems. LOCATOR Angled Abutment compatibility is demonstrated through reverse engineering of OEM devices and verified for functional performance via ISO14801 testing of the LOCATOR Angled Abutment with the smallest diameter OEM implant to ensure that the abutments fit and perform as intended.

Indication for Use

The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient.

IMPLANT COMPATIBILITY

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
LAA 15°, Straumann, BLX	Straumann	3.5, 3.75, 4.0, 4.5	BLX	Regular Base	2.9	Bone Level
		5.0, 5.5, 6.5	BLX	Wide Base	2.9	Bone Level

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
LAA 15°, Nobel (NP)	Nobel	3.5	NobelActive, NobelParallel CC, NobelReplace CC	Narrow Platform	3.0	Conical
LAA 15°, Nobel (RP)		4.3	NobelActive, NobelParallel CC, NobelReplace CC	Regular Platform	3.5	Conical
LAA 15°, Neodent (GM)	Neodent	3.5, 3.75, 4.0, 5.0, 6.0	Helix GM	N/A	3.0	Conical / Grand Morse
		3.5, 4.3, 5.0	Drive GM	N/A		Conical / Grand Morse
		3.5, 3.75, 4.0, 5.0	Titamax GM	N/A		Conical / Grand Morse
LAA 15°, TSV	ZimVie	3.7 & 4.1 Green	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	3.5	Internal Hex
		4.7 Purple	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	4.5	Internal Hex

v. Predicate Device Comparison

The following table compares the Indications for Use and key technological characteristics of the subject and predicate device:

Characteristic / Feature	Zest Anchors, Inc. LOCATOR Angled Abutment (Subject Device – K24xxxx)	Zest Anchors, Inc. LOCATOR Angled Abutment (Predicate Device – K233587)	ZIMMER DENTAL HEX-LOCK PREPARED ABUTMENT (STRAIGHT & ANGLED) (*Reference Device #1* – K052600)	NOBEL BIOCARE AB SBF 15 ESTHETIC ABUTMENT 1MM NP, MODEL 33699, SFB 15 ESTHETIC ABUTMENT 1MM RP, MODEL 33701, CFB 15 ESTHETIC ABUTMENT 2MM (*Reference Device #2* – K062749)	JJGC Industria e Comercio de Materiais Dentarios SA Neodent® Implant System – GM Line (Conventional abutments) (*Reference Device #3 – K163194)*	Comparison
Reason for predicate or reference	n/a	Design of Locator Angled Abutment	Zimmer TSV connection	Nobel NP/RP connection	GM implant/abutment connection	Predicate is unchanged and reference device is added for expanding compatibility.

Indication for use	The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient. A complete Implant Manufacturer's compatibility table is provided in the Instructions For Use.	The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient. The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K233587.	The Zimmer Dental Hex-Lock Prepared Straight Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The Zimmer Dental HexLock Prepared Angled Abutment is used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Either abutment can be used for a single or multiple-unit restoration.	Nobel Biocare's SFB and CFB Angled Abutments are premanufactured prosthetic components directly connected to the SFB & CFB endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	Indications for Use for GM conventional abutments: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	**Same:** The subject and predicate devices have the same indication for use.
Restoration Type	Full or partial, fixed and removable, restorations	Full or partial, fixed and removable, restorations	Full arch or partial restorations	Full arch or partial restorations	Full arch or partial restorations	**Same:** The subject and predicate devices have the same restoration type.
FDA Product Code	NHA (Abutment, Implant, Dental, Endosseous) 21 CFR 872.3630	NHA (Abutment, Implant, Dental, Endosseous) 21 CFR 872.3630	NHA (Abutment, Implant, Dental, Endosseous) 21 CFR 872.3630	NHA (Abutment, Implant, Dental, Endosseous) 21 CFR 872.3630	NHA (Abutment, Implant, Dental, Endosseous) 21 CFR 872.3630	**Same:** The subject and predicate devices have the same FDA product code
	DESIGN					
Abutment Height	2.5 mm to 7.5 mm	2.5 mm to 7.5 mm	1.5 - 6.5 mm	1.75mm, 3mm	0.8- 5.5mm	**Same.** Predicate, reference, and subject abutment height are the same.
Abutment Type	Angled	Angled	Straight and Angled	Straight and Angled	Straight	**Same.** Predicate, and subject abutment angles are the same.
Abutment Angled	15°	15°	0 and 17°	0°, 15°	0°, 17°, 30°	**Same.** Predicate, and subject abutment angles are same.
Abutment Screw	M1.6 x 0.35 Thread type (Nobel NP, Neodent GM) M2.0 X 0.4-6g	M1.6 x 0.35 Thread type	#1-72 UNF 2A Zimmer (ZimVie) Thread type	M1.6 x 0.35 Thread type (Nobel NP) M2.0 X 0.4-6g Thread type (Nobel RP)	M1.6 X 0.35-6g (Neodent GM) Thread type	**Similar.** Critical abutment screw features are similar to

	Thread type (Nobel RP) #1-72 UNF 2A Zimmer(ZimVie) Thread type					each reference device.
	Materials					
Abutment And Abutment Screw Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	TAV (Ti-6Al-4V)	Ti-6Al-4V ELI	Titanium Alloy, Ti-6Al-4V ELI	**Same**: subject, and predicate are made from the same material - titanium (Ti-6Al-4V)
Device Material Surface Treatment	TiN	TiN	Partially anodized / TiN coated	NA	NA	**Same**. Predicate and subject device use identical surface treatment process
	Sterilization					
Sterile	Moist heat end user sterilization	Moist heat end user sterilization	Delivered sterile by EO exposure	Moist heat end user sterilization	Delivered sterile by EO exposure	**Same**. Predicate and subject device are both supplied non-sterile.

vi. Summary of Non-Clinical Performance Testing

The critical features were identified on the OEM components (implant bodies, abutments, and abutment fixation screws), which are required for proper function. Using calibrated equipment with the appropriate accuracy the critical features were measured and documented. Using the data collected, including the variations, the specifications for the design were created. These specifications were reviewed for manufacturability. All critical tolerances were verified functionally in OEM implants.

Fatigue testing according to ISO 14801: 2016 was performed for the tallest abutment cuff height LOCATOR Angled Abutment along with the smallest diameter OEM implant.

The LOCATOR Angled Abutments are made of Ti-6Al-4V ELI with a TiN coating, identical to the predicate device. TiN coating performance was tested per ASTM F1044 and ASTM F1147.

The packaging of the LOCATOR Angled Abutments is similar to the packaging of the predicate device, consisting of the LOCATOR angled abutment placed in a vial and sealed in a polybag, along with a parallel post (class I device) used to visually confirm the desired abutment orientation. Additionally, some packaged configuration will include the LOCATOR Angled Abutment Screw packaged in a separate vial and sealed in the same polybag as the abutment and parallel post. Packaging and shipping validation

testing was completed where the LOCATOR Angled Abutment worst case device and packaging were undamaged after the test, as desired.

The cleaning and sterilization are identical to the predicate device cleared under K233587.

MR compatibility testing was conducted previously per ASTM F2052-21, ASTM F2213-17, ASTM F2182-19, ASTM F2119-07, and FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment” on abutment and implant components made of Ti-6Al-4V and designed with similar features as the LOCATOR Angled Abutments of this 510(K) submission. The tests that were conducted are Force: static magnetic field induced displacement force, Torque: static magnetic field induced torque, Heating: Radiofrequency field (RF) induced heating, Image Quality: susceptibility induced image artifacts, Heating: Gradient field induced heating, and Vibration: Gradient field induced vibration. The results have been leveraged for the LOCATOR Angled Abutment where engineering analysis established that the LOCATOR Angled Abutment does not create a new worst-case scenario.

An assessment for biocompatibility per ISO 10993-1 was conducted using testing from K072878 and additional cytotoxicity testing per ISO 10993-5 cleared under K233587 was provided in this submission.

No other new testing was performed as a part of this submission for the determination of substantial equivalence.

vii. Substantial Equivalence

The risk management activities and results of the testing described above provide reasonable assurance that the subject devices have demonstrated substantial equivalence to the predicate devices in the that they share the same intended use and principles of operation, use the same materials and manufacturing processes, and utilize the same fundamental design including identical prosthetic attachment features.