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

June 3, 2024

Re: K233587
Trade/Device Name: LOCATOR Angled Abutment (Various)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 3, 2023
Received: May 6, 2023

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.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233587

Device Name

LOCATOR Angled Abutment (Various)

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

Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
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

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.

510(K) Summary – K233587

LOCATOR Angled Abutment

i. General Information on Submitter

Applicant: Zest Anchors, LLC
Address: 2875 Loker Avenue, East
Carlsbad, CA 92010 USA
Telephone: 800-487-1357
Contact Person: David Lin
Contact Title: Sr. Regulatory Affairs Specialist
Email: regulatoryaffairs@zestdent.com
Date Prepared: May 31, 2024

ii. General Information on Device

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

iii. Predicate Device

Predicate Device	**510(k) Number**
Locator High Retention Attachment System (LOCATOR FIXED): Zest Anchors, LLC	K213391
Reference Devices	**510(k) Number**
Straumann BLX Line Extension - New Abutments: Institut Straumann AG	K190040
LOCATOR Implant Anchor Abutment: Zest Anchors, LLC	K072878
Straumann® BLX Implant System	K173961 K191256 K181703 K210855 K212533

iv. Description of Device

The purpose of this submission is to obtain marketing clearance for the LOCATOR Angled Abutment. The LOCATOR Angled Abutment is designed to be used with LOCATOR FIXED and LOCATOR Attachment Systems 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 abutment bodies with an integrated abutment screw. The attachment features are identical compared to LOCATOR Abutments of the LOCATOR High Retention Attachment System (LOCATOR FIXED), cleared in K213391. The LOCATOR Angled Abutment is compatible with Straumann BLX Implant System cleared in K173961. 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 uses identical attachment features as the LOCATOR Abutments, but instead of the attachment features being aligned coaxially, the interfacing features are provided at a 15 degree angle to allow for angle correction, substantially equivalent to the device of K190040. The LOCATOR Angled Abutments and integrated abutment screw are manufactured from titanium (Ti-6Al-4V). The LOCATOR Angled Abutment body is titanium nitride (TiN) coated, identical to LOCATOR Abutments.

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

Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
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

v. Predicate Device Comparison

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

Characteristic / Feature	***LOCATOR Angled Abutment* (Subject Device – K233587)**	**Locator High Retention Attachment System (*Predicate Device* – K213391)**	**Straumann BLX Line Extension – New abutments (*Reference Device #1* – K190040)**	**LOCATOR Implant Anchor Abutment (*Reference Device #2* – K072878)**	**Comparison**
Reason for predicate or reference	**n/a**	Fixed arch restoration indication	Abutment angulation feature	Design of abutment attachment features	Predicate is unchanged and reference device is added for angulation feature.
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. The LOCATOR Angled Abutment is compatible with Straumann BLX Implant System RB/WB Ø 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	The High Retention Attachment System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system.	The Straumann Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants.	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.	**Similar:** The subject and predicate devices have a similar indication for use.
Restoration Type	Fixed and removable	Fixed	Fixed and removable	Removable	**Similar:** In addition to a Fixed restoration type as indicated for the predicate device, the subject device is also indicated for a removable 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	**Same:** The subject and predicate devices have the same FDA product code
DESIGN					
Abutment Height	2.5 mm to 7.5 mm	N/A	1.5mm to 6.5mm	0 - 6.0 mm	**Similar.** Predicate, reference, and subject abutment height are similar.
Abutment Type	Angled	N/A	Straight and Angled	Straight	**Similar.** Predicate, reference, and subject abutment angles are similar.

Abutment Angled	15°	N/A	0° and 15°	0°	**Similar.** Predicate, reference, and subject abutment angles are similar.
Abutment Screw	M1.6 x 0.35 Thread, .069" Thread Depth, Ø.062" Screw Body Diameter, 90° Screw Head Taper	N/A	M1.6 x 0.35 Thread, .069" Thread Depth, Ø.062" Screw Body Diameter, 90° Screw Head Taper	N/A	**Same.** Predicate reference of critical abutment screw features are the same.
Materials					
Abutment And Abutment Screw Material	Ti-6Al-4V ELI	N/A	TAV (Ti-6Al-4V)	Ti-6Al-4V ELI	**Same**: subject, predicate, and reference devices are made from the same material - titanium (Ti-6Al-4V)
Device Material Surface Treatment	TiN	N/A	TiN	TiN	**Same**. Predicate and subject device use identical surface treatment process
Sterilization					
Sterile	Moist heat end user sterilization	Moist heat end user sterilization	Moist heat end user sterilization	Moist heat end user sterilization	**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 TiN coated. TiN coating performance was tested per ASTM F1044 and ASTM F1147.

The packaging of the LOCATOR Angled Abutments is equivalent to the packaging of the predicate device. Packaging and shipping validation testing was completed where the LOCATOR Angled Abutment worst case device and packaging were undamaged after the test, as desired.

Cleaning and sterilization are leverage in K072878 and this 510(k).

MR compatibility testing was conducted per ASTM F2052-15, 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”. 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.

An assessment for biocompatibility per ISO 10993-1 was conducted using testing from K072878 and additional cytotoxicity testing per ISO 10993-5 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 utilize the same materials and fundamental designs and also have the same intended use and principles of operation.