April 15, 2021

Zest Anchors LLC
Marysa Loustalot
Sr. Regulatory Affairs Specialist
2875 Loker Avenue East
Carlsbad, California 92010

Re: K203701
Trade/Device Name: Locator® Overdenture Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: March 19, 2021
Received: March 22, 2021

Dear Marysa Loustalot:

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 Steen
Assistant Director
DHT1B: Division of Dental 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)*
K203701

Device Name
The LOCATOR® Overdenture Implant System

Indications for Use *(Describe)*
The LOCATOR® Overdenture Implant Ssystem is designed to retain overdentures or partial dentures in the mandible or maxilla. Immediate loading is indicated when good primary stability has been achieved and with appropriate occlusal loading.

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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April 08, 2021

I. SUBMITTER

Zest Anchors, LLC
2875 Loker Ave. East.
Carlsbad, CA 92010
Phone: +1 (760) 743-7744
Contact: Marysa Loustalot ext. 596
Date Prepared: April 8, 2021

II. DEVICE INFORMATION

Device / Trade Name: LOCATOR® Overdenture Implant System
Common Name: Dental Implant System
Classification Name: Endosseous dental implant
Regulatory Classification: Class II, 21 CFR 872.3640
Product Code: DZE

III. PREDICATE DEVICE(s)

Primary Predicate: LOCATOR® Overdenture Implant System (K120198)

Reference Device(s): Legacy2, Legacy3, Legacy4, SimplyLegacy2, SimplyLegacy3 Dental Implants (K192221)

IV. DEVICE DESCRIPTION

The LOCATOR Overdenture Implant (LODI) was originally cleared under K120198. This submission is to add additional implant sizes to the LODI family that for distinction purposes, will hereinafter be called the Standard Ridge LOCATOR Overdenture Implant (LODI) System. The added implant sizes are listed in **Table 1.0** below:

Table 1.0 Subject Device Sizes

	LENGTH			
DIAMETER	8mm	10mm	12mm	14mm
3.5mm	x	x	x	x
3.9mm	x	x	x	x
4.4mm	x	x	x	x
4.9mm	x	x	x	x

Identical to K120198, the subject LODI Standard Ridge System is designed to retain overdentures of partial dentures in the mandible or maxilla. The System includes a threaded and tapered endosseous dental implant that is made from

the identical material, 6Al-4V ELI Titanium, and maintains its conformance to ASTM F136. The implant surface is roughened by Resorbable Blast Media (RBM) up to the abutment seating platform by the same manufacturing processes with the same manufacturing equipment as the existing LODI implant.

Additional wording was added to the Indications for Use statement for clarification purposes only. The Subject device's Indications for Use statement remains within scope of that cleared in K120198.

V. INDICATIONS FOR USE

The LOCATOR® Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla. Immediate loading is indicated when good primary stability has been achieved and with appropriate occlusal loading.

VI. SUBSTANTIAL EQUIVALENCY COMPARISON

FEATURES	SUBJECT	PREDICATE	REFERENCE DEVICE
510(k) Number	K203701	K120198	K192221
Device Name	LOCATOR Overdenture Implant (LODI) System	LOCATOR Overdenture Implant (LODI) System	Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3
Manufacturer	Zest Anchors, LLC	Zest Anchors, LLC	Implant Direct Sybron Manufacturing, LLC
Indications for Use	The LOCATOR® Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla. Immediate loading is indicated when good primary stability has been achieved and with appropriate occlusal loading.	The LOCATOR® Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla	These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Product Code	DZE	DZE	DZE
Classification	Class II	Class II	Class II
Regulation	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
RX / OTC	RX	RX	RX
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Ti 6Al-4V ELI

FEATURES	SUBJECT	PREDICATE	REFERENCE DEVICE
Material Surface Treatment	Resorbable Blast Media	Resorbable Blast Media	Soluble Blast Media
Diameter (Ø)	3.5mm, 3.9mm, 4.4mm, 4.9mm	2.4mm and 2.9mm	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm
Length	8mm, 10mm, 12mm, 14mm	10mm, 12mm, 14mm, 16mm	6mm, 8mm, 10mm, 11.5mm, 13mm 16mm

VII. PERFORMANCE TESTING

ATTRIBUTE TEST	DISCUSSION / RESULTS
Mechanical Properties - Body Type - Thread Type - Tip Type	- Identical Threaded and Tapered Body Type as Predicate - Thread type is a Dual Lead compared to the variable single lead of the Predicate. A dual lead thread does not create a new worst case regarding implant performance or strength. - Blunted (Predicate was sharp): The blunted tip of the Subject stops the implant from advancing past the drilled depth.
Corrosion Testing	N/A – Implant and implant attachment are made from the same type of material (titanium alloy); therefore, the implant will see no effects from galvanic corrosion. Titanium alloy is inherently corrosion resistant; therefore, the implant will see no effects of corrosion of the base metal.
Clinical Studies	No clinical studies are provided as part of this 510(k) submission.
Biocompatibility	The category, contact, and contact duration per ISO 10993-1 Table A.1 are the same for the Subject and Predicate device. The increased surface are of the device does not alter the ISO 10993-1 medical device categorization and therefore does not impact the biocompatibility profile of the LODI implant cleared under K120198. The biocompatibility of Ti-6AL-4V ELI remains unchanged from that of the Predicate.
Sterilization	Validation testing per ISO 11137-2:2015 was conducted to ensure that the Standard Ridge LODI Implant can also be sterilized in the same manner as the predicate implant by 25 kGy to achieve a sterility assurance level (SAL) of 10^{-6}.
Cleanability	The Total Organic Carbon and cytotoxicity test result demonstrated that the new worst-case implant, the Standard Ridge LODI 4.9mm implant, meets the acceptance criteria for HFE cleaning, HNO_3 cleaning, and IPA cleaning.
Fatigue Testing	Due to the larger cross-sectional area of the subject device, the identical finishing, material and manufacturing processes, it can be concluded that the subject device does not introduce a new worst case in respect to fatigue strength. Therefore, the fatigue testing reported in 510(k) K120198 remains applicable to the subject device.
Shelf-Life	The Subject device is supplied sterile in standard plastic tray with Tyvek™ lid using the same validated processes and materials as the Predicate. Accelerated aging conducted on the Predicate device as the worst case (2.9mm X 10mm with 4mm Cuff Height LOCATOR Abutment) validated for a period to to 5 years. The Subject device does not introduce a new worst case and therefore falls within the scope of the Predicate Shelf-Life testing.
Surface Treatment	The Resorbable Blast Media used for the implant surface treatment is the identical process and material used on the predicate implant cleared under K120198.
Endotoxin Testing	The method of detection for bacterial endotoxin uses the kinetic turbidimetric and chromogenic techniques per USP <85>, USP <161>, and AAMI ST72, with a limit of 20 EU/Device.

VIII. CONCLUSION

The Standard Ridge LODI System is identical to the LODI System cleared under K120198 in terms of intended use, system components, materials, and packaging. The equivalency of the Standard Ridge LODI System to the original LODI System has been demonstrated through verification and validation activities.