September 2, 2020

Ivory Super Holdco, Inc.
Zest Anchors, LLC
Marysa Loustalot
Sr. Regulatory Affairs Specialist
2875 Locker Ave East
Carlsbad, California 92010

Re: K200827
Trade/Device Name: LOCATOR R-Tx
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 28, 2020
Received: August 31, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200827

Device Name
LOCATOR R-Tx®

Indications for Use *(Describe)*
The LOCATOR R-Tx® Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla. LOCATOR R-Tx Attachment System is compatible with the following implant systems:

Implant Manufacturer:	Implant System:	Implant Diameters (Ø mm):
Ace Surgical	Infinity OCTAGON	(3.3, 4.1, 4.8)
	Infinity TRI-CAM	(3.5, 4.3, 5.0)
	Infinity External Hex	(3.3, 3.75, 4.0, 4.75)
	Infinity Internal Hex	(3.7, 4.1, 4.7, 5.1)
Avinent	Biomimetic Ocean	(3.3, 3.5, 4.0, 4.5, 5.0)
	Biomimetic Coral	(3.3, 3.8, 4.0, 4.2, 4.8)
Biohorizons	Tapered Internal	(3.0)
	Tapered Plus	(3.8)
	Laser-Lok	(3.0)
Biomet 3i	3iT3, NanoTite, OSSEOTITE	(3.25, 3.75, 4.0)
Blue Sky Bio	Quattro	(3.3, 4.1, 4.8)
	One Stage	(3.3, 4.1, 4.8)
Camlog	SCREW-LINE ROOT-LINE 2	(3.3, 3.8, 4.3, 5.0)
	SCREW-LINE	(3.3, 3.8, 4.3, 5.0)
Dentsply	Astra Tech OsseoSpeed EV	(3.6, 4.2, 4.8)
	Xive Frialit-2	(3.4, 3.8, 4.5, 5.5)
	Ankylos C/X	(3.5)
	Astra Tech OsseoSpeed TX	(3.5, 4.0, 4.5, 5.0)
Hiossen, Inc.	SS	(3.5, 4.0, 4.5)
	ET, TS	(3.5, 4.0, 4.5, 5.0, 6.0, 7.0)
	US	(3.5, 3.3, 4.5, 4.0, 5.0, 6.0, 7.0)
Implant Direct	Swish Plus	(4.1, 4.8)
	SwishTapered	(4.1, 4.8)
	InterActive	(3.2, 3.7, 4.3, 5.0)
	ReActive	(3.7, 4.2, 4.7, 5.7)
	Replant	(3.5, 4.3, 5.0)
	Legacy 1, 2, 3, 4	(3.7, 4.2)
	Legacy 2, 3, 4	(3.2, 4.7, 5.2)
	Legacy 1, 3	(5.7)
	Legacy 2, 4	(5.7, 7.0)
	Legacy 1	(4.7)
IDS	MegaGen Any Ridge	(3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0)
Keystone	PrimaConnex	(3.5, 4.1, 5.0)
	Genesis	(3.5)
	TILOBEMAXX	(7.0, 8.0, 9.0)
MIS	C1	(3.3, 3.75, 4.2)
	V3	(3.3, 3.9, 4.3, 5.0)
	SEVEN	(3.3)
	M4	(3.3)

Nobel	Replace, Replace Select, NobelSpeedy	(3.5, 4.3, 5.0)
	NobelActive, NobelParallel CC, NobelReplace CC	(3.5, 4.3, 5.5)
	Branemark, Nobel Speedy, Groovy	(3.3, 3.75, 4.0, 5.0)
OCO Biomedical	Engage	(3.25, 4.0, 5.0)
Southern Implants	Tri-Nex	(3.5, 4.3, 5.0)
	Tri-MAX7	(7.0)
	External Hex	(3.75, 4.0, 5.0, 5.1, 6.0, 7.0, 8.0)
Straumann	Roxolid SLActive, Roxolid SLA	(3.3, 4.1, 4.8)
Zimmer	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	(3.7, 4.1, 4.7, 6.0)
	Spline Reliance Cylinder	(3.25, 4.0, 5.0)
	Spline Twist	(3.75)

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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I. SUBMITTER

Zest Anchors, LLC
2875 Loker Ave. East.
Carlsbad, CA 92010
Phone: +1 (760) 743-7744
Contact: Marysa Loustalot ext. 596
Date Prepared: September 1, 2020

II. DEVICE INFORMATION

Device / Trade Name: LOCATOR R-Tx®
Common Name: Dental Implant Abutment
Classification Name: Endosseous dental implant abutment
Regulatory Classification: Class II, 21 CFR 872.3630
Product Code: NHA

III. PREDICATE DEVICE

The subject device is identical to the predicate device in terms of manufacturability, cleaning/disinfection/sterilization, biocompatibility, packaging, and shipping. The subject device is similar in design to the predicate device and identical to the predicate in regards to the abutment-implant interface as described in K150295.

IV. DEVICE DESCRIPTION

LOCATOR R-Tx implant attachment system, consists of abutments, nylon or PEEK liners and denture caps to serve in a similar function to LOCATOR as a resilient attachment for endosseous implants. All LOCATOR R-Tx abutments are made of titanium alloy and have the same coronal double ridge retention design that attaches to the overdenture component. The threaded apical end of the abutment connects to the implant and is specific to each compatible implant system and diameter. LOCATOR R-Tx is designed to accommodate a path of insertion on implants that are divergent up to 30° unless prohibited by the implant manufacturer. LOCATOR R-Tx abutments are provided with either TiCN or TiN coating and available in six cuff heights (1, 2, 3, 4, 5, and 6 mm). The abutments are provided in diameters 3.0 – 6.5 mm as shown below in the compatibility table.

V. INDICATIONS FOR USE

The LOCATOR R-Tx® Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla. The LOCATOR R-Tx Attachment System is compatible with the following implant systems:

Implant Manufacturer:	Implant System:	Implant Diameters (Ø mm):
Ace Surgical	Infinity OCTAGON	(3.3, 4.1, 4.8)
	Infinity TRI-CAM	(3.5, 4.3, 5.0)
	Infinity External Hex	(3.3, 3.75, 4.0, 4.75)
	Infinity Internal Hex	(3.7, 4.1, 4.7, 5.1)
Avinent	Biomimetic Ocean	(3.3, 3.5, 4.0, 4.5, 5.0)
	Biomimetic Coral	(3.3, 3.8, 4.0, 4.2, 4.8)
Biohorizons	Tapered Internal	(3.0)
	Tapered Plus	(3.8)
	Laser-Lok	(3.0)
Biomet 3i	3iT3, NanoTite, OSSEOTITE	(3.25, 3.75, 4.0)
Blue Sky Bio	Quattro	(3.3, 4.1, 4.8)
	One Stage	(3.3, 4.1, 4.8)
Camlog	SCREW-LINE ROOT-LINE 2	(3.3, 3.8, 4.3, 5.0)
	SCREW-LINE	(3.3, 3.8, 4.3, 5.0)
Dentsply	Astra Tech OsseoSpeed EV	(3.6, 4.2, 4.8)
	Xive Frialit-2	(3.4, 3.8, 4.5, 5.5)
	Ankylos C/X	(3.5)
	Astra Tech OsseoSpeed TX	(3.5, 4.0, 4.5, 5.0)
Hiossen, Inc.	SS	(3.5, 4.0, 4.5)
	ET, TS	(3.5, 4.0, 4.5, 5.0, 6.0, 7.0)
	US	(3.5, 3.3, 4.5, 4.0, 5.0, 6.0, 7.0)
Implant Direct	Swish Plus	(4.1, 4.8)
	SwishTapered	(4.1, 4.8)
	InterActive	(3.2, 3.7, 4.3, 5.0)
	ReActive	(3.7, 4.2, 4.7, 5.7)
	Replant	(3.5, 4.3, 5.0)
	Legacy 1, 2, 3, 4	(3.7, 4.2)
	Legacy 2, 3, 4	(3.2, 4.7, 5.2)
	Legacy 1, 3	(5.7)
	Legacy 2, 4	(5.7, 7.0)
	Legacy 1	(4.7)
IDS	MegaGen Any Ridge	(3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0)
Keystone	PrimaConnex	(3.5, 4.1, 5.0)
	Genesis	(3.5)
	TILOBEMAXX	(7.0, 8.0, 9.0)
MIS	C1	(3.3, 3.75, 4.2)
	V3	(3.3, 3.9, 4.3, 5.0)
	SEVEN	(3.3)
	M4	(3.3)

Nobel	Replace, Replace Select, NobelSpeedy	(3.5, 4.3, 5.0)
	NobelActive, NobelParallel CC, NobelReplace CC	(3.5, 4.3, 5.5)
	Branemark, Nobel Speedy, Groovy	(3.3, 3.75, 4.0, 5.0)
OCO Biomedical	Engage	(3.25, 4.0, 5.0)
Southern Implants	Tri-Nex	(3.5, 4.3, 5.0)
	Tri-MAX7	(7.0)
	External Hex	(3.75, 4.0, 5.0, 5.1, 6.0, 7.0, 8.0)
Straumann	Roxolid SLActive, Ro	(3.3, 4.1, 4.8)
Zimmer	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	(3.7, 4.1, 4.7, 6.0)
	Spline Reliance Cylinder	(3.25, 4.0, 5.0)
	Spline Twist	(3.75)

VI. COMPARISON TO PREDICATE DEVICE

Attribute	Subject Device	Predicate Device	SE?
510(k) Number	TBD	K150295	N/A
Name	The LOCATOR R-Tx® Attachment System	The LOCATOR R-Tx® Attachment System	Y
Manufacturer	Zest Anchors, LLC	Zest Anchors, LLC	Y
Indications for Use	The LOCATOR R-Tx® Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	The LOCATOR® R-Tx Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	Y; Clarification only to add additional compatible implants
Product Code	NHA	NHA	Y
Classification	II	II	Y
Regulation	21 CFR 872.3630	21 CFR 872.3630	Y
RX/OTC	RX	RX	Y
Features	Female Abutment Nylon Male Denture Cap	Female Abutment Nylon Male Denture Cap	Y
Mode of Operation	Abutment design that connects to a housing embedded in a denture ridge, which nylon inserts are used to allow connection and disconnection of the denture to the abutment for "removable" denture solution for the patient	Abutment design that connects to a housing embedded in a denture ridge, which nylon inserts are used to allow connection and disconnection of the denture to the abutment for "removable" denture solution for the patient	Y
Design			
Abutment Diameter (mm)	2.75 – 6.0	3.0 – 7.0	Y
Abutment Angle	Straight	Straight	Y
Divergence Allowance	30°	30°	Y
Material			
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Y
Prosthetic Retention Component	Nylon or Peek	Nylon or Peek	Y

VII. PERFORMANCE TESTING

The abutment-implant interface of the R-Tx abutment is verified to be compatible through either OEM signed abutment drawings, OEM implant drawings, or established compatibility demonstrated with the use of LOCATOR abutments through mutual contractual agreements with the OEM. Once the specifications and tolerances have been identified, the R-Tx abutment-implant interface is then verified through engineering analysis and documented per Zest internal procedures for Line Extensions. No additional performance testing is required as compatibility confirms that all testing (i.e., biocompatibility, sterilization, surface characterization) provided in predicate K150295 remains applicable to the new abutment-implant connection, with no impact to the risk profile of the LOCATOR R-Tx Attachment System.

VIII. CONCLUSION

The minor modifications made for implant compatibility on the LOCATOR R-Tx abutment design does not introduce a new worst case as the abutments remain tissue supported, the changes do not identify new risks, nor do the changes impact the risk profile of the device cleared under K150295. Therefore, the new abutment-implant connections and modified abutment designs identified within this Special 510(k) are substantially equivalent to those cleared in K150295.