

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 <u>Federal Register</u>.

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 <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). 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 (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) 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

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:

Ace Surgical Infinity OCTAGON $(3,3,4,1,4,8)$ Infinity TRI-CAM $(35,5,43,5,0)$ Infinity External Hex $(3,3,3,5,4,0,4,75)$ Infinity Internal Hex $(3,3,3,5,4,0,4,5,5,0)$ Biomimetic Ocean $(3,3,3,5,4,0,4,5,5,0)$ Biomimetic Coral $(3,3,3,3,4,0,4,2,4,8)$ Biohorizons Tapered Internal Tapered Plus $(3,0)$ Biomet 3i 3173, NanoTite, OSEOTITE Blue Sky Bio Quatro One Stage $(3,3,4,1,4,8)$ Camlog SCREW-LINE ROOT-LINE 2 SCREW-LINE $(3,3,3,4,3,5,0)$ Dentsply Astra Tech OsseoSpeed EV Xive Frialit-2 $(3,4,3,3,4,5,5,5)$ Ankylos C/X $(3,5,4,0,4,5,5,0)$ Missen, Inc. SS String Tered $(4,1,4,8)$ Implant Direct Swish Plus Minder Quatro $(3,5,4,3,5,0)$ Replant $(3,5,4,3,5,0)$ Replant $(3,5,4,3,5,0)$ Inglant Direct Swish Plus $(4,1,4,8)$ Implant Direct Swish Plus $(3,2,3,7,4,3,5,0)$ Replant	Implant Manufacturer:	Implant System:	Implant Diameters (Ø mm):
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V3 (3.3, 3.9, 4.3, 5.0) SEVEN (3.3)		TILOBEMAXX	(7.0, 8.0, 9.0)
SEVEN (3.3)	MIS	C1	(3.3, 3.75, 4.2)
		V3	(3.3, 3.9, 4.3, 5.0)
M4 (3.3)		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 Infinity Internal Hex	(3.3, 3.75, 4.0, 4.75)
Avinant	Biomimetic Ocean	(3.7, 4.1, 4.7, 5.1)
Avinent	Biomimetic Ocean Biomimetic Coral	(3.3, 3.5, 4.0, 4.5, 5.0) (3.3, 3.8, 4.0, 4.2, 4.8)
Biohorizons	Tapered Internal	(3.0)
Bioliolizolis	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)
Dide Sky Dio	One Stage	(3.3, 4.1, 4.8)
Camlog	SCREW-LINE ROOT-LINE 2	(3.3, 3.8, 4.3, 5.0)
Cunnog	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	
Nama	The LOCATOR R-Tx [®] The LOCATOR R-T		37	
Name	Attachment System	Attachment System	Y	
Manufacturer	Zest Anchors, LLC	Zest Anchors, LLC	Y	
	The LOCATOR R-Tx®	The LOCATOR [®] R-Tx		
	Attachment System is	Attachment System is	Y;	
	designed for use with	designed for use with	Clarification	
Indications	overdentures or partial	overdentures or partial	only to add	
for Use	dentures, retained in whole	dentures, retained in whole or	additional	
	or in part, by endosseous	in part, by endosseous	compatible	
	implants in the mandible or	implants in the mandible or	implants	
	maxilla.	maxilla.		
Product Code	NHA	NHA	Y	
Classification	II	II	Y	
Regulation	21 CFR 872.3630	21 CFR 872.3630	Y	
RX/OTC	RX	RX	Y	
	Female Abutment	Female Abutment		
Features	Nylon Male	Nylon Male	Y	
	Denture Cap	Denture Cap		
	Abutment design that	Abutment design that connects		
	connects to a housing	to a housing embedded in a		
	embedded in a denture ridge,	denture ridge, which nylon		
	which nylon inserts are used	inserts are used to allow		
Mode of Operation	to allow connection and	connection and disconnection	Y	
	disconnection of the denture	of the denture to the abutment		
	to the abutment for	for "removable" denture		
	"removable" denture solution	solution for the patient		
	for the patient	solution for the patient		
Design			•	
Abutment Diameter	2.75 - 6.0	3.0 - 7.0	Y	
(mm)			1	
Abutment Angle	Straight	Straight	Y	
Divergence Allowance	30°	30°	Y	
Material				
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Y	
Prosthetic Retention	Nylon or Peek	Nylon or Peek	Y	
Component	Tryfoli Of I CCK	TryIon Of I CCK	1	

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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.