January 11, 2022

Zest Anchors, LLC
% Melissa Burbage
RA Sr Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K213391
Trade/Device Name: High Retention Attachment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 15, 2021
Received: October 15, 2021

Dear Melissa Burbage:

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 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213391

Device Name

High Retention Attachment System

Indications for Use *(Describe)*

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 High Retention Attachment System is compatible with the following implants:

Implant Manufacturer	Implant System	Implant Diameter
Ace Surgical	Infinity OCTAGON	3.3, 4.1, 4.8
	Infinity TRI-CAM	3.5, 4.3, 5.0
	Infinity Internal Hex	3.7, 4.1, 4.7, 5.1
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
Straumann	Roxolid SLActive, Roxolid SLA	3.3, 4.1, 4.8
Zimmer Dental	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.

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

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510(k) Summary

K213391

High Retention Attachment System

Zest Anchors, LLC

January 10, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Zest Anchors, LLC 2875 Loker Ave. East Carlsbad, CA 92010 Telephone: +1 (442) 244-4835
Official Contact	Mark Stavro, Regulatory Affairs Director
Representative/Consultant	Melissa Burbage Kevin A. Thomas, PhD; Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: mburbage@paxmed.com kthomas@paxmed.com; flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	High Retention Attachment System
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K151789, LOCATOR F-Tx Attachment System, Zest Anchors, LLC

Reference Devices
K072878, LOCATOR Implant Anchor Abutment, Zest Anchors, LLC
K200827, LOCATOR R-Tx Attachment System, Zest Anchors, LLC

INDICATIONS FOR USE STATEMENT

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.

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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
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Camlog	SCREW-LINE ROOT-LINE 2	3.3, 3.8, 4.3, 5.0
	SCREW-LINE	3.3, 3.8, 4.3, 5.0
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	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
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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
Straumann	Roxolid SLActive, Roxolid SLA	3.3, 4.1, 4.8
Zimmer Dental	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

SUBJECT DEVICE DESCRIPTION

The High Retention Attachment System is a system that provides rigid connection of fixed partial and full arch restorations (fixed/detachable hybrid dentures) to endosseous dental implants. It is designed to accommodate a path of insertion on implants to accommodate a divergence of up to 20° per implant and no more than 40° of divergence between implants. The components are similar to the LOCATOR Implant Anchor Abutment, cleared in K072878; however, the retention and removal of the inserts is similar to that of the LOCATOR F-Tx Attachment System cleared in K151789.

The High Retention Attachment System consists of abutments, attachment housings, inserts, laboratory processing tools and seating and removal tools. Abutments, attachment housings and inserts are Class II subject devices (Product Code NHA) and laboratory processing tools and seating and removal tools are Class I accessories (Product Code NDP). The abutments are provided in various cuff heights with the implant/abutment connection specific to the OEM implant. The subject device abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)* and are TiN (titanium nitride) coated.

PERFORMANCE DATA

Non-clinical testing data referenced/relied upon to demonstrate substantial equivalence included: sterilization validation and biocompatibility testing. Both the material and Titanium Nitride (TiN) coating have the same specifications, processes, and are manufactured in the same facilities as the predicate F-Tx Attachment System (K151789) and predicate LOCATOR device (K072878).

Non-clinical testing data submitted to demonstrate substantial equivalence included: mechanical denture retention testing. The mechanical testing demonstrated that the retention force of the High Retention Attachment System was greater than retention force of the predicate device K151789.

The subject abutment-implant interface of the High Retention Attachment System 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 performance testing is required, as demonstrated for the predicate LOCATOR R-Tx Attachment System (K200827).

EQUIVALENCE TO MARKETED DEVICES

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Comparison**
	Zest Anchors, Inc. High Retention Attachment System K213391	Zest Anchors, LLC LOCATOR® F-Tx Attachment System K151789	Zest Anchors, Inc. LOCATOR® Implant Anchor Abutment K072878	Zest Anchors, Inc. LOCATOR R-Tx® Attachment System K200827	
Indications for Use	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 LOCATOR® F-Tx 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 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.	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.	Same as Predicate and Reference
Design					
Abutment Platform Diameter	2.3 mm to 7.0 mm, Multiple Systems	3.0 mm to 7.0 mm; Multiple Systems	2.3 mm to 7.0 mm, Multiple Systems	3.0 mm to 7.0 mm; Multiple Systems	Same as Reference
Abutment Angle	Straight	Straight	Straight	Straight	Same
Abutment/ Implant Interface	Conical, External Hex, Internal Hex, Internal Multi Lobe	Conical, External Hex, Internal Hex, Internal Multi Lobe	Conical, External Hex, Internal Hex, Internal Multi Lobe	Conical, External Hex, Internal Hex, Internal Multi Lobe	Same
Divergence Allowance	20°/40° (except when not allowed by the implant manufacturer)	20°	20°	30°/60°	Same
Prosthesis Attachment Type	PEEK Insert retained in Denture Attachment Housing	PEEK Retention Ball attached to Denture Attachment Housing	Nylon Insert retained in Denture Attachment Housing	Nylon Male Retention Cap	Same as Predicate
Materials					
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Same
Abutment Coating	TiN	TiN, TiCN	TiN	TiN, TiCN	Same
Prosthetic Retention Component	PEEK	PEEK	Nylon	Nylon	Same as Predicate

CONCLUSION

The subject devices, the primary predicate device and reference devices have the same intended use and similar technological characteristics. They encompass a similar range of physical dimensions, are manufactured from the same materials, and are to be sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.