DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 4, 2016

Zest Anchors, LLC
c/o Kevin A. Thomas, Ph.D.
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K151789
Trade/Device Name: LOCATOR® F-Tx Attachment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 2, 2016
Received: February, 03, 2106

Dear Dr. Thomas:

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. 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 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151789

Device Name

LOCATOR® F-Tx Attachment System

Indications for Use *(Describe)*

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® F-Tx Attachment System is compatible with the following implants:

Implant Manufacturer	Connection Type / Platform
Astra Tech	OsseoSpeed Plus EV: 3.6, 4.2, 4.8 mm
BioHorizons	Internal Hex: 3.0, 3.5, 4.5, 5.7 mm
Biomet 3i	Osseotite® Certain®: 3.4, 4.1, 5.0, 6.0 mm
Camlog	Camlog, Conelog: 3.3, 3.8, 4.3, 5.0 mm
	iSy: 3.8, 4.4, 5.0 mm
Dentsply	Ankylos®: 3.5, 4.5, 5.5, 7.0 mm
MIS Implants	Internal Hex: 3.75, 4.5 mm
Nobel Biocare	NobelActive™: 3.0, 3.5, 3.9 mm
	Replace™ Select: 3.5, 4.3, 5.0, 6.0 mm
	Brånemark: 3.5, 4.1, 5.1 mm
Straumann	Bone Level: 3.3, 4.1, 4.8 mm
	Standard: 4.8, 6.5 mm
Zimmer	Tapered Screw-Vent®: 3.5, 4.5, 5.7 mm

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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510(k) Summary
ZEST Anchors, LLC
LOCATOR® F-Tx Attachment System

March 1, 2016

ADMINISTRATIVE INFORMATION

Manufacturer Name	Zest Anchors, LLC 2061 Wineridge Place Escondido, CA 92029 Telephone: +1 (760) 743-7744 ext. 140 Fax: +1 (760) 743-7975
Official Contact	Annie Wright Regulatory Affairs Manager
Representative/Consultant	Kevin A. Thomas, PhD Linda K. Schulz, BSDH, RDH PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: KThomas@paxmed.com LSchulz@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	LOCATOR® F-Tx Attachment System
Common Name	Dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulation	Class II, 21 CFR 872.3630
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate is K072878.
The reference predicate device for the TiCN coating is K150295.
The reference predicate devices for the abutment-implant interface compatibilities are K120414, K071638, K093321, K143022, K063341, K000100, K083496, K113779, K133991, K041509, K040807, K071370, K102436, K020646, K022562, K062129, K130222, and K061410.

INTENDED USE

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® F-Tx Attachment System is compatible with the following implants:

Implant Manufacturer	Connection Type / Platform
Astra Tech	OsseoSpeed Plus EV: 3.6, 4.2, 4.8 mm
BioHorizons	Internal Hex: 3.0, 3.5, 4.5, 5.7 mm
Biomet 3i	Osseotite® Certain®: 3.4, 4.1, 5.0, 6.0 mm
Camlog	Camlog, Conelog: 3.3, 3.8, 4.3, 5.0 mm
	iSy: 3.8, 4.4, 5.0 mm
Dentsply	Ankylos®: 3.5, 4.5, 5.5, 7.0 mm
MIS Implants	Internal Hex: 3.75, 4.5 mm
Nobel Biocare	NobelActive™: 3.0, 3.5, 3.9 mm
	Replace™ Select: 3.5, 4.3, 5.0, 6.0 mm
	Brånemark: 3.5, 4.1, 5.1 mm
Straumann	Bone Level: 3.3, 4.1, 4.8 mm
	Standard: 4.8, 6.5 mm
Zimmer	Tapered Screw-Vent®: 3.5, 4.5, 5.7 mm

DEVICE DESCRIPTION

The LOCATOR® F-Tx Attachment System is for rigid connection of fixed, partial and full arch restorations on endosseous dental implants using a snap-in or screw-retained attachment system. The system includes abutments and healing caps. LOCATOR F-Tx abutments are compatible with the implant systems, connection types, and platform sizes listed above, and are provided in various gingival cuff heights ranging from 1 to 6 mm. LOCATOR F-Tx System 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)*. LOCATOR F-Tx abutments may be provided with an optional coating of either TiCN (titanium carbon nitride) or TiN (titanium nitride). LOCATOR F-Tx System Healing Caps are made of PEEK.

PERFORMANCE DATA

Performance testing to demonstrate substantial equivalence included methods described in the following standards: ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices;* ISO 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1;* ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;* ISO 10993-5 *Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity;* and

ISO 10993-12 *Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials.* Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation testing, characterization and biocompatibility testing of the TiCN coating, biocompatibility testing of the PEEK Healing Caps, and mechanical denture retention testing. The mechanical testing demonstrated the retention strength of the LOCATOR F-Tx Attachment System when using the High Retention Balls was statistically greater than the tensile force created when masticating worst case sticky food ($p<0.05$). No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

LOCATOR F-Tx Attachment System is substantially equivalent in indications and design principles to the legally marketed predicate devices shown in the following table.

Table of Predicate Devices

K072878	Locator Implant Anchor Abutment for Endosseous Dental Implant	Zest Anchors, Inc.
K150295	LOCATOR RTx	Zest Anchors, LLC
Predicates for Compatible Implant Systems		
K120414	OsseoSpeed™ Plus	Astra Tech AB
K071638	BioHorizons Tapered Internal Implant System	BioHorizons Implant Systems, Inc.
K093321	BioHorizons Laser-Lok 3.0 Implant System	BioHorizons Implant Systems, Inc.
K143022	BioHorizons Tapered Internal Implants	BioHorizons Implant Systems, Inc.
K063341	3i OSSEOTITE® Certain® Dental Implants	Implant Innovations, Inc.
K000100	CAMLOG Rootform Implant System	Altatec Biotechnologies
K083496	CAMLOG Implant System Modified Implants and Abutments	Altatec GmbH
K113779	CONELOG® Implant System	Altatec GmbH
K133991	iSy® Implant System	Altatec GmbH
K041509	ANKYLOS® Dental Implant System	Friadent GmbH
K040807	MIS Dental Implant System	MIS - Implant Technologies Ltd.
K071370	NobelActive Internal Connection Implant	Nobel Biocare AB
K102436	NobelActive 3.0	Nobel Biocare AB
K020646	Replace™ HA Coated Implant	Nobel Biocare USA Inc.
K022562	Various Brånemark System Implants	Nobel Biocare AB
K062129	P.004 Implants	Institut Straumann AG
K130222	Straumann® Dental Implant System	Straumann USA, LLC
K061410	Zimmer Dental Implant System	Zimmer Dental Inc.

The primary predicate is K072878.
The reference predicate device for the TiCN coating is K150295.
The reference predicate devices for the abutment-implant interface compatibilities are: K120414, K071638, K093321, K143022, K063341, K000100, K083496, K113779, K133991, K041509, K040807, K071370, K102436, K020646, K022562, K062129, K130222, and K061410.

Comparison of Subject Device and Primary Predicate Device

Comparison	Subject Device	Primary Predicate Device
	Zest Anchors, LLC LOCATOR® F-Tx Attachment System K151789	Zest Anchors, Inc. Locator Implant Anchor Abutment for Endosseous Dental Implant K072878
Indications for Use	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. *See page 2 for complete list of compatible 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.
Design		
Abutment Platform Diameter	3.0 mm to 7.0 mm; Multiple Systems	2.5 mm to 6.5 mm, Multiple Systems
Abutment Angle	Straight	Straight
Abutment/Implant Interface	Conical, External Hex, Internal Hex, Internal Multi Lobe	Conical, External Hex, Internal Hex, Internal Multi Lobe
Divergence Allowance	20°	20°
Prosthesis Attachment Type	PEEK Retention Ball attached to Denture Attachment Housing	Nylon Insert engaged to Denture Attachment Housing
Material		
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Abutment Coating	TiN, TiCN	TiN
Prosthetic Retention Component	PEEK	Nylon

LOCATOR F-Tx is substantially equivalent to Locator (K072878) and the reference predicate LOCATOR RTx (K150295) in that it uses the identical interface for compatible implant systems. The previous interfaces have been demonstrated through contractual agreements with the OEM implant manufacturers. The compatible dental implants with the corresponding interfaces are listed above in the **Table of Predicate Devices**. LOCATOR F-Tx and Locator (K072878) are each provided with varying cuff heights. The abutment/implant interfaces of all LOCATOR F-Tx abutments are identical to those of the corresponding Locator (K072878) abutments.

The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use of abutments. The subject device and primary predicate device abutments are intended to be used in conjunction with dental implants for the purpose of supporting partial or full arch restorations. The subject device is for use with fixed hybrid restorations removed only by the clinician, whereas the primary predicate device is for use with restorations that may be removed by the patient.

The subject device is indicated for fixed hybrid implant restorations using a snap-in connection. The LOCATOR F-Tx snap-in connection is similar to the Locator (K072878), but has a PEEK retention ball attached to the center of the denture attachment housing instead of a nylon insert

on the abutment. Removal of the hybrid denture restoration by the clinician requires the use of the LOCATOR F-Tx denture removal tool.

The TiN coating for the subject device is the same as that used on the predicate Locator device (K072728). The TiCN coating for the subject device is the same as that used on the reference predicate LOCATOR RTx (K150295).

CONCLUSION

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.