DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 24,2015

Zest Anchors, LLC
% Linda Schulz
Regulatory Affairs
Paxmed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K150295
Trade/Device Name: LOCATOR RTx
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 17, 2015
Received: June 18, 2015

Dear Linda Schulz:

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 801); 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), 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,

Erin 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)*

K150295

Device Name

LOCATOR® RTx

Indications for Use *(Describe)*

The LOCATOR® RTx 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® RTx Attachment System is compatible with the following implant systems.

Implant Manufacturer:	System:
BioHorizons	Internal Hex (3.0, 3.5, 4.5, 5.7 mm)
	External Hex (3.5, 4.0, 5.0 mm)
Biomet 3i	Certain Internal (3.4, 4.1, 5.0, 6.0 mm)
	External Hex (3.4, 4.1, 5.0, 6.0 mm)
Camlog	Camlog and 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)
	XiVE/FRIALIT-2 (3.4, 3.8, 4.5, 5.5 mm)
	Astra Tech OsseoSpeed EV (3.6, 4.2, 4.8 mm)
MIS Implants	Internal Hex (3.75, 4.5 mm)
Nobel Biocare	Replace: Internal (3.5, 4.3, 5.0, 6.0 mm),
	NobelActive: Internal Conical (3.0, 3.5, 4.3, 5.0 mm),
	Brånemark: External Hex (3.3, 3.75, 4.0, 5.0 mm)
Straumann	Tissue Level (3.5, 4.8, 6.5 mm)
	Bone Level (3.3, 4.1, 4.8 mm)
Zimmer	Tapered Screw Vent: Internal Hex (3.5, 4.5, 5.7 mm)
	Spline (3.25, 4.0, 5.0 mm)
	Swiss Plus:Internal Octagon (3.8, 4.8 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.

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

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510(k) Summary
Zest Anchors, LLC
LOCATOR® RTx
K150295

July 23, 2015

ADMINISTRATIVE INFORMATION

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Official Contact	Annie Wright Regulatory Affairs Manager
Representative/Consultant	Linda K. Schulz, BSDH, RDH 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: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	LOCATOR® RTx
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

INTENDED USE

The LOCATOR® RTx 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® RTx Attachment System is compatible with the following implant systems.

Implant Manufacturer	**Connection**
BioHorizons	Internal Hex (3.0, 3.5, 4.5, 5.7 mm) External Hex (3.5, 4.0, 5.0 mm)
Biomet 3i	Certain Internal (3.4, 4.1, 5.0, 6.0 mm) External Hex (3.4, 4.1, 5.0, 6.0 mm)
Camlog	Camlog and 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) XiVE/FRIALIT-2 (3.4, 3.8, 4.5, 5.5 mm) Astra Tech OsseoSpeed EV (3.6, 4.2, 4.8 mm)
MIS Implants	Internal Hex (3.75, 4.5 mm)
Nobel Biocare	Replace: Internal (3.5, 4.3, 5.0, 6.0 mm) NobelActive: Internal Conical (3.0, 3.5, 4.3, 5.0 mm) Brånemark: External Hex (3.3, 3.75, 4.0, 5.0 mm)
Straumann	Tissue Level (3.5, 4.8, 6.5 mm) Bone Level (3.3, 4.1, 4.8 mm)
Zimmer	Tapered Screw Vent: Internal Hex (3.5, 4.5, 5.7 mm) Spline (3.25, 4.0, 5.0 mm) Swiss Plus: Internal Octagon (3.8, 4.8 mm)

DEVICE DESCRIPTION

LOCATOR® RTx 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 RTx 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 RTx is designed to accommodate a path of insertion on implants that are divergent up to 30° unless prohibited by the implant manufacturer. LOCATOR RTx abutments are provided with either TiCN or TiN coating and are available in six cuff heights (1, 2, 3, 4, 5, and 6 mm). They are provided in diameters 3.0 – 7.0 mm as shown in the compatibility table above.

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 10993-10 *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*. Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation testing, biocompatibility testing of the TiCN coating, and characterization testing of the TiCN coating. The performance data included in this submission demonstrate substantial equivalence to the predicate devices listed below.

EQUIVALENCE TO MARKETED DEVICE

LOCATOR RTx is substantially equivalent to LOCATOR in that it uses the identical interface for compatible implant systems and it is a nylon or PEEK liner overdenture system with varying cuff heights.

Primary predicate: Zest Anchors, Inc., Modification to Locator Implant Anchor cleared under K072878.
Reference Device: Astra Tech AB, OsseoSpeed Plus cleared under K120414.

510(k) Number	Implant System Compatibility
K063341	Biomet 3i Osseotite® Certain®
K063286	Biomet 3i Osseotite®
K061410	Zimmer Tapered Screw-vent®
K010073	Zimmer Spline
K082639	Zimmer SwissPlus
K103089	MIS
K062129	Straumann Bone Level
K130222	Straumann Standard
K020646	Nobel Biocare Replace™ Select
K071370 K102436	Nobel Biocare NobelActive™
K022562	Nobel Biocare Brånemark
K041509	Dentsply Friadent® Ankylos®
K073075	Dentsply Friadent® Frialit/XiVE®
K120414	Astra Tech OsseoSpeed Plus (EV)
K000100	Camlog Rootform Implant System
K083496	Camlog Implant System
K113779	Conelog Implant System
K133991	Camlog iSy Implant System
K071638 K093321 K143022	BioHorizons Internal
K030463	BioHorizons External Hex

	Subject Device	Primary Predicate Device	Additional Predicate Device
	Zest Anchors, LLC LOCATOR® RTx	Zest Anchors, Inc. LOCATOR Implant Anchor Abutment for Endosseous Dental Implant K072878	Astra Tech AB OsseoSpeed Plus K120414
Indications for Use	The LOCATOR® RTx Implant 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 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.	Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.
Design			
Abutment Diameter, mm	3.0 to 7.0	3.25 to 6.5	3.0 to 5.4
Abutment Angle	Straight	Straight	Straight
Abutment/Implant Interface	Conical, External Hex, Internal Hex, Internal Multi Lobe	Conical, External Hex, Internal Hex, Internal Multi Lobe	Internal Taper
Divergence Allowance	30°/60° (except when prohibited by implant manufacturer)	20°/40°	33°/66°
Prosthesis Attachment Type	Nylon or PEEK male retention cap	Nylon male retention cap	Screw-retained
Material			
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Prosthetic Retention Component	Nylon or PEEK	Nylon	NA

The subject device is the same in all features as the primary predicate with the exception of the compatible implant/abutment interface. The subject device has the same divergence allowance as the reference device. The subject device has a resilient overdenture prosthesis attachment and the reference device is for a screw-retained prosthesis.

CONCLUSION

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

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same processes.