JUN 2 5 2014 K133327

510(k) Summary

Zest Anchors, LLC

SATURNO™ Overdenture Implant System

October 28, 2013

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	Linda K. Schulz, BSDH, RDH Kevin A. Thomas, PhD 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 KThomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	SATURNO™ Overdenture Implant System
Common Name	Dental implant
Classification Name	Implant, endosseous, root-form
Classification Regulation	Class II, 21 CFR 872.3640
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

The SATURNO™ Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla. The SODI is used to restore masticatory function for the patient and may be suitable for immediate function if sufficient primary stability of the implant is achieved at the time of placement.

DEVICE DESCRIPTION

The SATURNO™ Overdenture Implant (SODI) System is a one-piece, self-tapping, threaded, root-form dental implant with the abutment portion being either straight or angled for overdenture prosthetic attachment. SODI implants are provided in three diameters (2.0, 2.4 and 2.9 mm), three lengths (10, 12 and 14 mm) and two cuff heights (2.0 and 4.0 mm). Each size SODI implant has a 1.8 mm attachment ball and is available with a straight or 20° angled abutment section.

EQUIVALENCE TO MARKETED DEVICE

Zest Anchors, LLC, LOCATOR® Overdenture Implant System - K120198;

IMTEC Corporation, IMTEC Sendax MDI and MDI Plus - K031106;

IMTEC Corporation, MDI MII One-Piece Implant 2.9 - K081653;

Intra-Lock International, Inc., Mini Drive-Lock™ Dental Implant System - K070601.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: engineering analysis, dimensional analysis, static and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. Fatigue testing demonstrated the subject device to be equivalent to or stronger than the tested predicate device.

The subject device and the predicate devices encompass the same range of physical dimensions and characteristics, including implant diameter, length, and surface treatment. Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. Clinical data were not submitted in this premarket notification.

In conclusion, SATURNO™ Overdenture Implant System 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 materials, and
- has similar packaging and is sterilized using the same materials and processes.

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

June 25, 2014

Zest Anchors, LLC
C/O Linda K. Schulz
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K133327
Trade/Device Name: SATURNO™ Overdenture Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 16, 2014
Received: June 18, 2014

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

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

Indications for Use

510(k) Number: K133327

Device Name: SATURNO™ Overdenture Implant System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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