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

October 2, 2015

Altatec GmbH
c/o Ms. Linda Schulz
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K151599
Trade/Device Name: iSy® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 1, 2015
Received: September 2, 2015

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 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" (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 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)*
K151599

Device Name

iSy® Implant System

Indications for Use *(Describe)*

iSy® Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. iSy® Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

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

Altatec GmbH
iSy® Implant System

September 1, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	Altatec GmbH Maybachstrasse 5 D-71299 Wimsheim, Germany Telephone: +49 7044 9445 0 Fax: +49 7044 9445 723
Official Contact	Colleen Boswell Director of RA/QA Ortho Organizers, Inc.
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	iSy® Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Name	Implant, endosseous, root form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640 Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

iSy® Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. iSy® Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

DEVICE DESCRIPTION

iSy Implant System implants are self-tapping, root form, tapered endosseous dental implants made of titanium. The implant has a smooth machined surface in the transgingival portion, and a Promote® surface on the endosseous portion. The subject device implants are provided in two lengths (7.3 and 16 mm) and three diameters (3.8, 4.4 and 5.0 mm). The subject device includes four abutment types, gingiva former, temporary abutment, Locator® and Esthomic Abutment. Abutments are compatible with all three diameters (3.8, 4.4 and 5.0 mm). The Esthomic abutment is available with three design angulations (0°, 15°, 20°). iSy® Implant System Abutments are intended for use as support for crowns, bridges or overdentures.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation according to : ISO 11137-1 *Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ISO 11137-2 *Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose*, 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*, and static and dynamic compression-bending testing according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants*.

Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

Primary Predicate:
Altatec GmbH, iSy® Implant System, K133991;
Reference Predicates:
Altatec GmbH, CAMLOG Implant System Modified Implants and Abutments, K083496;
Altatec GmbH, CAMLOG Logfit Prosthetic System, K071213;
Astra Tech AB, OsseoSpeed™ Plus, K120414; and
Zest Anchors, Inc, Modification To Locator Implant Anchor, K072878;
Zest Anchors, LLC, Locator RTx, K150925.

Comparison of the technological characteristics of the subject device and predicate devices is shown in the Table of Substantial Equivalence below.

Table of Substantial Equivalence

	Subject Device	Predicate Device			
	Altatec GmbH iSy® Implant System	Altatec GmbH iSy® Implant System K133991	Altatec GmbH CAMLOG Implant System Modified Implants and Abutments K083496	Astra Tech AB OsseoSpeed™ Plus K120414	Zest Anchors, Inc Modification to: Locator Implant Anchor K072878
Design					
Implant Length, mm	7.3, 16	9, 11, 13	9.0, 11.0, 13.0, 16	6, 8, 9, 11, 13, 15, 17	NA
Implant Diameter, mm	3.8, 4.4, 5.0	3.8, 4.4, 5.0	3.3, 3.8, 4.3, 5.0, 6.0	3.0, 3.6, 4.2,4.8, 5.4	NA
Abutment Diameter, mm	3.8, 3.9, 4.8, 5.4, 5.9, 6.6	6.5	3.3, 3.8, 4.3, 5.0, 6.0	3.0, 3.6, 4.2, 4.8, 5.4	3.25 to 6.5
Abutment Angle	Straight, 15°, 20°	Straight, up to 30°	Straight, 15°, 20°	Straight, 15°, 20°, 30°	Straight
Material					
Implant	CP Ti Gr 4	CP Ti Gr 4	CP Ti Gr 4	CP Ti Gr 4	NA
Abutments and Abutment Screw	Ti-6Al-4V ELI;	Ti-6Al-4V ELI; Zirconia	Ti-6Al-4V ELI; Zirconia	Ti-6Al-4V ELI; Zirconia, Gold alloy	Ti-6Al-4V ELI

The purpose of this submission is to expand the iSy Implant System components with the addition of two new lengths and four abutment designs. The additional implant lengths have the same design as the previously cleared iSy implants and have lengths equivalent to K120414 and K083496. The implant base is identical to the implant base previously cleared. The new abutment designs are equivalent to those cleared in K083496, K120414 and K072878.

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 materials, and
- has similar packaging and is sterilized using the same materials and processes.