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

February 17, 2015

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

Re: K143337
Trade/Device Name: CONELOG® Titanium base CAD/CAM
Regulation Number: 21 CFR 872.4630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 19, 2014
Received: November 20, 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 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,

Tina Kiang -S

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

Enclosures

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)*
K143337

Device Name

CONELOG® Titanium base CAD/CAM

Indications for Use *(Describe)*

CONELOG® Titanium base CAD/CAM
- Implant-prosthetic titanium abutment for CONELOG® implants with conical abutment connection, as a bonding base for hybrid abutments.
- The Titanium base CAD/CAM for implant Ø 3.3 mm is designed only for hybrid abutments in the area of the upper lateral incisors and lower central and lateral incisors.

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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K143337

510(k) Summary

Altatec GmbH

CONELOG® Titanium base CAD/CAM

February 12, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Altatec GmbH Maybachstrasse 5 D-71299 Wimsheim, Germany Telephone: +49 7044 9445 0 Fax: +49 7044 9445 723
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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:	CONELOG® Titanium base CAD/CAM
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Classification Regulations:	21 CFR 872.3630, Class II
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

CONELOG® Titanium base CAD/CAM

- Implant-prosthetic titanium abutment for CONELOG® implants with conical abutment connection, as a bonding base for hybrid abutments.
- The titanium base CAD/CAM for implant Ø3.3mm is designed only for hybrid abutments in the area of the upper lateral incisors and lower central and lateral incisors

DEVICE DESCRIPTION

CONELOG Titanium base CAD/CAM is an abutment designed to be used with the Sirona CAD/CAM System in Coris ZI meso L and meso S to fabricate a hybrid abutment with an angle up to 20°.The Titanium base CAD/CAM is available in four implant platform sizes (3.3 mm 3.8 mm, 4.3 mm, and 5.0 mm), two gingival heights (0.8 mm or 2.0 mm) and is supplied with the corresponding screw. All design parameters are according to the cleared Sirona CAD/CAM System parameters.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: 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

Altatec GmbH submits the following information in this Premarket Notification to demonstrate, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Altatec GmbH, iSy® Implant System - K133991;
Altatec GmbH, CONELOG® Implant System - K113779;
Altatec GmbH, CAMLOG® Implant System Modified Implants and Abutments - K083496; and
Sirona Dental Systems GmbH, Sirona Dental CAD/CAM System - K111421.

The primary predicated device for this submission is K133991. The subject device and the predicate devices encompass the same range of physical dimensions and characteristics, including implant diameter and length, and similar surface treatments. Any differences in the technological characteristics between the subject and predicate devices do not raise different issues of safety or effectiveness.
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 materials and processes.