DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 31, 2016

ALTATEC GmbH
c/o Ms. Linda Schultz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K153779
Trade/Device Name: Abutment for Bridges
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: II
Product Code: NHA
Dated: December 30, 2015
Received: December 31, 2015

Dear Ms. Schultz:

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,

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

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)* K153779

Device Name

Abutment for Bridges

Indications for Use *(Describe)*

CAMLOG® and CONELOG®
CAMLOG® and CONELOG® Abutments are intended to be used to fabricate prosthetic restorations in conjunction with CAMLOG® and CONELOG® implants to support prostheses in the maxillary and/or mandibular arch.

iSy®
iSy® Abutments are intended to be used to fabricate prosthetic restorations in conjunction with iSy® implants to support prostheses in the maxillary and/or mandibular arch.

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
ALTATEC GmbH
Abutment for Bridges

March 30, 2016

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Abutment for Bridges
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

PREDICATE INFORMATION

Primary Predicate
ALTATEC GmbH, CONELOG® Implant System - K113779

Reference Predicates
ALTATEC GmbH, iSy® Implant System - K133991
ALTATEC GmbH, CAMLOG Implant System Modified Implants and Abutments - K083496

INTENDED USE

CAMLOG® and CONELOG®
CAMLOG® and CONELOG® Abutments are intended to be used to fabricate prosthetic restorations in conjunction with CAMLOG® and CONELOG® implants to support prostheses in the maxillary and/or mandibular arch.

iSy®
iSy Abutments are intended to be used to fabricate prosthetic restorations in conjunction with iSy® implants to support prostheses in the maxillary and/or mandibular arch.

DEVICE DESCRIPTION

Abutment for Bridges is a straight abutment designed for multi-unit, cement-retained restorations. It is available with two gingival heights (0.8 and 2.0 mm) for CONELOG and iSy and one gingival height for CAMLOG.

Abutment for Bridges is available for CAMLOG, CONELOG and iSy Implant Systems. It is available in five CAMLOG platform diameters (3.3 mm, 3.8 mm, 4.3 mm, 5.0 mm, and 6.0 mm), four CONELOG platform diameters (3.3 mm, 3.8 mm, 4.3 mm and 5.0 mm), and one iSy interface connection.

The Temporary Abutment is a straight, one-piece titanium abutment for cement-retained provisional restorations. It is available in a non-indexed bridge version for CAMLOG, CONELOG and iSy, and an indexed crown version for CAMLOG implant system.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation according to 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*, and ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and reference to the applicant's own predicate devices in K113779, K133991, and K0823496 for demonstration of biocompatibility.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Abutment for Bridges is equivalent to the abutments in K113779 and K083496. They are straight abutments designed for cement retained restorations. The primary design difference is that the Abutment for Bridges has no anti-rotation feature in the implant/abutment connection or on the post for restoration.

Temporary Abutment is equivalent to the temporary abutment in K113779. The primary difference is that the Temporary Abutment has no anti-rotation feature because it is a multi-unit abutment.

	Subject Device	Primary Predicate Device
	ALTATEC GmbH Abutment for Bridges K153779	ALTATEC GmbH CONELOG® Implant System K113779
Indications for Use	CAMLOG® and CONELOG® CAMLOG® and CONELOG® Abutments are intended to be used to fabricate prosthetic restorations in conjunction with CAMLOG® and CONELOG® implants to support prostheses in the maxillary and/or mandibular arch. iSy® iSy Abutments are intended to be used to fabricate prosthetic restorations in conjunction with iSy® implants to support prostheses in the maxillary and/or mandibular arch.	Implant Indications for Use CONELOG® Implant System Implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. CONELOG® 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. CONELOG® Implants with 3.3 mm diameter have the following additional specific indications: These are an alternative in cases where the alveolar ridge width is only 5 – 6 mm. Because of their lower mechanical strength compared with larger diameter implants, they should only be used under the following conditions: • As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors. • An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal extensions. • Implants of Ø 3.3 mm are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account. • Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø 3.3 mm implants. • The healing time for Ø 3.3 mm implants is at least 12 weeks. CONELOG® Implants with 7 mm length have the following additional specific indications: CONELOG® SCREW-LINE Implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional. Abutment Indications for Use CONELOG ® Abutments are intended to be used to fabricate prosthetic restorations in conjunction with CONELOG implants to support prostheses in the maxillary and/or mandibular arch. Vario SR Indications for Use CONELOG® Vario SR components for crown and bridge restorations: • Occlusal screw-retained crown, bridge and bar constructions on CONELOG® implants in the anterior and posterior region of the maxilla and mandible CONELOG® Vario SR components for bar restorations: • Anchorage of implant-supported full dentures for the edentulous maxilla in conjunction with 4 or more CONELOG® implants and in the edentulous mandible in conjunction with 2 or 4 or more CONELOG® implants.

	Subject Device	Primary Predicate Device
	ALTATEC GmbH Abutment for Bridges K153779	ALTATEC GmbH CONELOG® Implant System K113779
Design		
Abutment/Implant Diameter, mm	3.3, 3.8, 4.3, 4.4, 5.0, 6.0	3.3, 3.8, 4.3, 5.0
Abutment Angle	Straight	Up to 20°
Restoration	Cement-retained	Screw-retained, Cement-retained
Material		
Abutments and Abutment Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI

The Indications for Use for the subject device differs from the identified primary predicate in that the submission device Indications for Use is a sub-set of the Indications for Use of the primary predicate. This does not change the intended use of the subject device as compared to the predicate because the subject device, a dental abutment, is a subset of the primary predicate, a complete implant system. The intended use of the subject device is similar to the intended use of the dental abutments cleared in the primary predicate.

Implant/abutment interfaces for CAMLOG, CONELOG and iSy subject device abutments are similar to the corresponding predicate device Implant Systems as identified in the primary and reference predicate devices. However, the lack of an anti-rotation feature does not affect the fit of the abutment to the corresponding implant and is further mitigated by the limitation of the Abutment for Bridges and non-indexed Temporary Abutment devices as multi-unit abutments.

CONCLUSION

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 to be sterilized using the same processes.

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