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

January 12, 2016

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

Re: K152509
Trade/Device Name: CAMLOG® and CONELOG® Abutments For Screw-retained Restorations (ASR)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 10, 2015
Received: December 11, 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" (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

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)*

Device Name

CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR)

Indications for Use *(Describe)*

CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR) are intended to support occlusal screw- retained prosthetic restorations in the upper jaw and lower jaw in conjunction with CAMLOG® and CONELOG® Implants.

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
CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR)

January 11, 2016

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	CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR)
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

CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR) are intended to support occlusal screw-retained prosthetic restorations in the upper jaw and lower jaw in conjunction with CAMLOG® and CONELOG® Implants.

PREDICATE INFORMATION

The primary predicate device is K133421.

Reference Predicates
K141871 - Straumann® Screw Retained Abutments
K073553 - CAMLOG Implant System Abutments
K083496 - CAMLOG Implant System Modified Implants and Abutments
K113779 - CONELOG® Implant System

DEVICE DESCRIPTION

Abutment for Screw-retained Restorations (ASR) is available with the Camlog or the Conelog implant/abutment interface. ASR Straight is provided in five platform diameters (3.3, 3.8, 4.3, 5.0 and 6.0 mm) and three gingival heights (0.5, 2.0 and 4.0 mm), for a total of 15 abutment options. ASR Angled is provided in four platform diameters (3.3, 3.8, 4.3, and 5.0 mm), four gingival heights (2.5, 3.5, 4.0 and 5.0 mm), and two angles (17° and 30°). Each of the angled designs is provided in a Type A option (anti-rotation cam alignment away from the abutment cone angle) or Type B option (anti-rotation cam alignment in the direction of the abutment cone angle), for a total of 32 abutment options. A healing cap, and a titanium cap for temporary or permanent restoration fabrication are available for all sizes. All ASR components are made from titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

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

The subject device is substantially equivalent in indications and design principles predicate devices shown above. Below are summary tables showing technical comparison between the subject device and the primary predicate devices.

	Indications for Use
Subject Device	
Altatec Gmbh CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR)	CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR) are intended to support occlusal screw-retained prosthetic restorations in the upper jaw and lower jaw in conjunction with CAMLOG® and CONELOG® Implants.
Primary Predicate Device	
Straumann USA, LLC Straumann® Magellan™ Abutment System K133421	The Straumann® Magellan™ abutments are indicated to be placed into Straumann® dental implants to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing function. Magellan™ abutments are indicated for screw-retained restorations.

	Subject Device	**Primary Predicate**	**Reference Predicate Devices**			
	Altatec Gmbh CAMLOG® and CONELOG® Abutments for Screw-retained Restorations (ASR)	Straumann USA, LLC Straumann® Magellan™ Abutment System K133421	Straumann USA, LLC Straumann® Screw Retained Abutments K141871	Altatec GmbH CAMLOG Implant System Abutments K073553	Altatec GmbH CAMLOG Implant System Modified Implants and Abutments K083496	Altatec Gmbh CONELOG® Implant System K113779
Design						
Prosthesis Attachment	Screw-retained	Screw-retained	Screw-retained	Screw-retained	Screw-retained	Screw-retained
Abutment Platform Diameter, mm	3.3 - 6.0	3.5 - 4.6	4.6	3.3 - 6.0	3.3 - 6.0	3.3 - 5.0
Abutment Angle	Straight to 30°	Straight to 30°	Straight to 30°	Straight to 20°	Straight to 20°	Straight to 20°
Material						
Abutment	Ti-6AL-4V ELI	Ti-6AL-7Nb	Ti-6AL-7Nb	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI

Abutment for Screw-retained Restorations (ASR) is substantially equivalent to the predicate devices in K133421 and K141871. K133421 is the primary predicate having straight and angled abutments (17° and 30°), multiple gingival heights (1.0 – 4.0 mm) and Type A and B indexing orientations. Straumann® Screw Retained Abutments K141871 adds angled abutments for the NC diameter implant. Both ASR and Straumann Screw-retained Abutment have a titanium cap designed for temporary or permanent restorations. The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use of abutments. Both abutments are being used in conjunction with dental implants for the purpose of supporting screw-retained dental prostheses.

CONCLUSIONS

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including length, diameter, height, and angle of the abutment. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

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