DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 14, 2016

Altatec Gmbh
% Linda Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K160784
Trade/Device Name: CAM Titanium Blanks
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 17, 2016
Received: August 18, 2016

Dear Linda 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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)*

K160784

Device Name

CAM Titanium Blanks

Indications for Use *(Describe)*

CAM Titanium Blanks are intended for the fabrication of abutments and healing caps on CAMLOG® SCREW-LINE and CAMLOG® ROOT-LINE implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CAMLOG® CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.

CAM Titanium Blanks are intended for the fabrication of abutments and healing caps on CONELOG® SCREW-LINE implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CONELOG® CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.

CAM Titanium Blanks are intended for the fabrication of abutments and healing caps/gingiva former on iSy® implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with iSy® CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.

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
CAM Titanium Blanks

September 12, 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, Henry Schein
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	CAM Titanium Blanks
Common Name	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 DEVICE INFORMATION

Primary Predicate
K150203, Medentika CAD/CAM Abutments, Medentika GmbH

Reference Predicates
K092341, Low Profile Abutment, Biomet 3i
K083496, CAMLOG® Implant System, Altatec GmbH
K113779, CONELOG® Implant System. Altatec GmbH
K133991, iSy® Implant System, Altatec GmbH

INDICATIONS FOR USE

CAM Titanium Blanks are intended for the fabrication of abutments and healing caps on CAMLOG® SCREW-LINE and CAMLOG® ROOT-LINE implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CAMLOG® CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.

CAM Titanium Blanks are intended for the fabrication of abutments and healing caps on CONELOG® SCREW-LINE implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CONELOG® CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.

CAM Titanium Blanks are intended for the fabrication of abutments and healing caps/gingiva former on iSy® implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with iSy® CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.

DEVICE DESCRIPTION

CAM Titanium Blanks are abutments with a prefabricated, precision interface (implant/abutment connection) and a screw channel suitable for the respective implant system. CAM Titanium Blanks are to be used by a CAMLOG validated milling center with CAD/CAM technology to fabricate a final finished customized abutment made of titanium alloy. Each patient-specific abutment is individually prescribed by the clinician as a temporary, permanent, single, or multi-unit abutment. Computer-aided manufacturing (CAM) techniques are used to process the cylinder portion above the implant connection into an individual abutment or healing cap/gingiva former design. The healing cap/gingival former is temporary and used during healing. Permanent abutments have straight and angled designs that can be used for crowns, bridges or overdentures.

CAM Titanium Blanks are available for CAMLOG SCREW-LINE and ROOT-LINE implants fitting five implant diameters (3.3, 3.8, 4.3, 5.0, 6.0 mm), for CONELOG SCREW-LINE implants fitting four implant diameters (3.3, 3.8, 4.3, 5.0 mm), and for the iSy implants with one connection fitting three implant diameters (3.8, 4.4, 5.0 mm).

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 17665-2; biological evaluation according to ISO 10993-1 by reference to K083496, K113779, and K133991; MR testing according to ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119; and static and dynamic compression-bending testing according to ISO 14801.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the predicate devices shown above. Below are summary tables comparing the Indications for Use and the technological characteristics of the subject device and the predicate devices.

Comparison of Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use</th></tr>
<tr><td>Subject Device

Altatec GmbH
CAM Titanium Blanks
K160784</td><td>CAM Titanium Blanks are intended for the fabrication of abutments and healing caps on CAMLOG® SCREW LINE and CAMLOG® ROOT-LINE implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.
CAM Titanium Blanks are intended for the fabrication of abutments and healing caps on CONELOG® SCREW-LINE implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.
CAM Titanium Blanks are intended for the fabrication of abutments and healing caps/gingiva former on iSy® implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.</td></tr>
<tr><td colspan="2">Predicate Devices</td></tr>
<tr><td>Primary Predicate Device

Medentika GmbH
Medentika CAD/CAM Abutments
K150203</td><td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>
Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td></tr>
<tr><td colspan="2">Reference Predicate Devices</td></tr>
<tr><td>Biomet 3i
Low Profile Abutment
K092341</td><td>Biomet 3i Low Profile Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained to the abutment.</td></tr>
<tr><td>Altatec GmbH
CAMLOG Implant System Modified Implants and Abutments
K083496</td><td>Camlog Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. Camlog 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.</td></tr>
<tr><td>Altatec GmbH
Conelog® Implant System
K113779</td><td>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 ful 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.</td></tr>
<tr><td>Altatec GmbH
iSy Implant System
K133991</td><td>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.</td></tr>
</table>

Comparison of Technological Characteristics

	Subject Device	**Primary Predicate**	**Reference Predicates**			
	Altatec GmbH CAM Titanium Blanks K160784	Medentika GmbH Medentika CAD/CAM Abutments K150203	Biomet 3i Low Profile Abutment K092341	Altatec GmbH CAMLOG Implant System K083496	Altatec GmbH Conelog Implant System K113779	Altatec GmbH iSy Implant System K133991
Prosthesis Attachment	Cement-retained	Cement-retained	Screw-retained	Screw-retained Cement-retained	Screw-retained Cement-retained	Screw-retained Cement-retained
Restoration type	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit
Corresponding Implant Platform Diameter (mm)	3.3 – 6.0	3.0 – 7.0	3.4 – 5.0	3.3 – 6.0	3.3 – 5.0	3.8 – 5.0
Abutment Angle	Straight, up to 30°	Straight, up to 30°	Straight, up to 30°	Straight, up to 20°	Straight, up to 20°	Straight, up to 20°
Abutment materials	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI, Zirconia	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Screw material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI

The subject device and the primary predicate K150203 have similar Indications for Use statements. The slight differences in language and details specific to each device do not change the intended use to support prosthetic restorations on endosseous dental implants. The reference predicate devices are included to support substantial equivalence of implant compatibility (K083496, K113779, K133991) and for abutment parameters (K092341), and also do not alter the intended use of the subject device.

CAM Titanium Blanks are available for three CAMLOG implant lines, CAMLOG®, CONELOG®, and iSy®. The implant/abutment interface connections are identical to the previously cleared CAMLOG® (K083496), CONELOG® (K113779), and iSy® (K133991) connections.

The design, material and intended use of CAM Titanium Blanks are substantially equivalent to that of the primary predicate Medentika CAD/CAM Abutments (K150203). The CAM Titanium Blanks and Medentika Preface both have a precision machined interface for the implant/abutment connection and are suited for CAD/CAM fabrication of customized endosseous dental implant abutments for single or multi-unit restorations. CAM Titanium Blanks and Medentika Preface abutments are indicated for a single or multi-unit restoration with an abutment angulation up to 30°. CAM Titanium Blank is available in diameters 3.3 mm – 6.0 mm, and Medentika Preface is available in diameters 3.0 mm – 7.0 mm.

Differences between the subject devices and the predicate devices in specific dimensions and compatible implant systems do not impact substanial equivalence. Minor differences in the language of the indications for use statement between the subject device and the predicate devices do not affect the intended use to provide abutments for use with endosseous dental implants to provide prosthetic support in the maxilla and mandible.

CONCLUSION

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 diameter and angle of the abutments. The subject and predicate devices are packaged in similar materials and are to be sterilized using similar methods.

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