# 510(k) Summary
# Altatec GmbH
# CONELOG® Implant System
# K113779

DEC 1 4 2012

November 20, 2012

ADMINISTRATIVE INFORMATION


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|---|---|
| Manufacturer Name: | Altatec GmbH<br>Maybachstrasse 5<br>D-71299 Wimsheim, Germany<br>Telephone: +49 7044 9445 0<br>Fax: +49 7044-9445 723 |
| Official Contact: | Tina Steffanie-Oak<br>Senior Regulatory Affairs Specialist, CAMLOG USA |
| Representative/Consultant: | Linda K. Schulz, BSDH, RDH<br>Kevin A Thomas, PhD<br>PaxMed International, LLC<br>11234 El Camino Real, Suite 200<br>San Diego, CA 92130<br>Telephone: +1 (858) 792-1235<br>Fax: +1 (858) 792-1236<br>Email: lschulz@paxmed.com<br>kthomas@paxmed.com |


DEVICE NAME AND CLASSIFICATION

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|---|---|
| Trade/Proprietary Name: | CONELOG® Implant System |
| Common Names: | Dental implants and dental implant abutments |
| Classification Name: | Implant, Endosseous, Root-form<br>Abutment, Implant, Dental, Endosseous |
| Classification Regulations: | 21 CFR 872.3640, 21 CFR 872.3630, Class II |
| Product Codes: | DZE, NHA |
| Classification Panel: | Dental Products Panel |
| Reviewing Branch: | Dental Devices Branch |

INTENDED USE

**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.

DEVICE DESCRIPTION

The purpose of this submission is to add an alternative to the CAMLOG® Implant System by the introduction of an implant line with a tapered implant abutment interface. The new line of implants and abutments is named the CONELOG® Implant System. The primary features of the current CAMLOG Implant System are a change from the tube-in-tube interface with a square cam design for anti-rotation to the tapered implant/abutment interface connection with three positioning cams and the addition of a 7.0 mm long implant. The three positioning cams of the CONELOG abutments are placed more apically

on the abutment shaft but are comparable in design principle to the three positioning cams of the CAMLOG Implant System. All other design features of the system remain the same.

The CONELOG implant system features an implant/abutment interface that includes a 7.5° taper with anti-rotation cams at the base of the connection. Components available with the CONELOG implant/abutment interface include the SCREW-LINE Promote® plus implant and cover screw, healing caps, Universal abutments, Telescope abutments, Esthomic® abutments, the Esthomic® abutment inset, temporary abutments, Gold-plastic abutments, Logfit® abutments, ball abutments, bar abutments and Vario SR abutments. All components correspond to previously cleared CAMLOG components with the tube-in-tube interface.

EQUIVALENCE TO MARKETED DEVICES

Altatec GmbH has demonstrated that, for the purposes of FDA's regulation of medical devices, the CONELOG® Implant System is substantially equivalent in indications and design principles to the following predicate devices:

Altatec GmbH, CAMLOG Implant System Modified Implants and Abutments cleared under K083496;

Altatec GmbH, CAMLOG® VarioSR Abutments cleared under K103252;

Altatec GmbH, Altatec CAMLOG Abutments and Healing Caps cleared under K051636;

Astra Tech, Inc., OsseoSpeed™ 4.0S - 6 mm cleared under K063779,

Sulzer Dental, Inc., Screw-Vent Dental Implant System cleared under K011028,

Implant Innovations, Inc., OSSEOTITE® Certain® Dental Implants cleared under K063341,

Bicon, LLC., Ø3.0 x 8 mm and Ø3.0 x 11 mm Bicon Implant 3.0mm cleared under K101849.

The CONELOG Implant System is an additional implant line to the CAMLOG Implant System using a tapered implant/abutment interface. A tapered implant/abutment interface is used for the Astra Tech implant system cleared under K063779 and many other implants that are cleared for marketing in the United States. Other than the interface and the addition of a 7.0 mm length implant, all the components of the CONELOG system have the same design and material as those cleared under, K083496, K103252 and K051636. The 7.0 mm implant is similar in design and length to the Astra Tech OsseoSpeed 4.0S - 6 mm, having a tapered connection and a treated surface. Other design features of the 7.0 mm implant are the same as the other implants in the CONELOG Implant System.

Mechanical testing, including static and dynamic compression-bending testing, has been perfomed according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants.*

In conclusion, the data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, the CONELOG Implant System 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.

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

December 14, 2012

Altatec GmbH
C/O Ms. Linda K. Schulz, BSDH, RDH
PaxMed International, Limited Liability Company
11234 El Camino Real, Suite 200
SAN DIEGO CA 92130

Re: K113779
Trade/Device Name: Conelog® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 7, 2012
Received: December 10, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Susan Runner DDS, MA 2012.12.14 11:48:37 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number: K113779

Device Name: CONELOG® Implant System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Susan Runner DDS, MA 2012.12.14 11:47:54 -05'00'

**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** _____

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: