K083496

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510(k) Summary

Altatec GmbH

JAN 30 2009

CAMLOG Implant System Modified Implants and Abutments

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Altatec GmbH Maybachstrasse 5 D-71299 Wimsheim, Germany Telephone: +49 7044 9445 0 Fax: +49 7044 9445 723
Official Contact:	Tina Steffanie-Oak CAMLOG USA Telephone: +1 (717) 335-7230 Fax: +1 (717) 335-7240 Email: Tina.Steffanie-Oak@henryschein.com
Representative/Consultant:	Linda K. Schulz or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA USA 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 Implant System Modified Implants and Abutments
Common Name:	Dental implant; Dental implant abutment
Classification Regulations:	Implant, endosseous, root-form; Endosseous dental implant abutment 21 CFR 872.3640; 21 CFR 872.3630
Product Codes	DZE, NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

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INTENDED USE

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.

DEVICE DESCRIPTION

The Camlog Implant System includes various sizes of threaded root-form dental implants and abutments intended to support prosthetic restorations in edentulous or partially edentulous patients. The implants can be placed immediately following extraction or after a healing period. If good primary stability is reached the implants may be immediately loaded. The complete system includes a variety of laboratory (burnout) copings, impression copings, analogs and other components intended to facilitate the preparation of prosthetic restorations.

EQUIVALENCE TO MARKETED PRODUCT

The components of the CAMLOG Implant System, including the modified implants and abutments, have the same basic design as the predicate devices. Overall, the CAMLOG 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 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
9200 Corporate Boulevard
Rockville MD 20850

Altatec GmbH
C/O Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

JAN 30 2009

Re: K083496
Trade/Device Name: CAMLOG Implant System Modified Implants and Abutments
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 21, 2008
Received: November 25, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CAMLOG Implant System Modified Implants and Abutments

Indications for Use:

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.

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

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