510(k) Summary

MAR - 5 2008

Altatec GmbH
CAMLOG Implant System Abutments

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Altatec GmbH Maybachstrasse 5 D-71299 Wimsheim, Germany Telephone: +49 7044-9445-0 Fax: +49 7044-9445-722
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 Abutments
Common Name:	Dental implant abutments
Classification Regulations:	Endosseous dental implant abutment 21 CFR 872.3630, Class II
Product Codes	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

CAMLOG Implant System Abutments are intended to be used to fabricate crowns and bridges in conjunction with CAMLOG dental implants to support prostheses in the maxillary and/or mandibular arch.

DEVICE DESCRIPTION

This submission covers a series of abutments for the CAMLOG Implant System, including a straight crown and bridge abutment, a prepable abutment, a conical abutment, a cast-on abutment, and a temporary abutment.

EQUIVALENCE TO MARKETED PRODUCT

Altatec GmbH demonstrated that, for the purposes of FDA's regulation of medical devices, CAMLOG Implant System Abutments are substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

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

MAR - 5 2008

Re: K073553
Trade/Device Name: CAMLOG Implant System Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 17, 2007
Received: December 18, 2007

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.

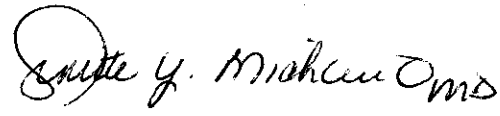
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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 Abutments

Indications for Use:

CAMLOG Implant System Abutments are intended to be used to fabricate crowns and bridges in conjunction with CAMLOG dental implants to support prostheses in the maxillary and/or mandibular arch.

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

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

510(k) Number: K073553