510(k) Summary

JAN 10 2011

Altatec GmbH
CAMLOG® Vario SR Abutments
January 3, 2011

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	CAMLOG® Vario SR Abutments
Common Name:	Dental implant abutments
Classification Regulations:	Endosseous dental implant abutment 21 CFR 872.3630, Class II
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

CAMLOG® Vario SR components for crown and bridge restorations:

- Occlusal screw-retained crown, bridge and bar constructions on CAMLOG® implants (with J and K article numbers) in the anterior and posterior region of the maxilla and mandible

CAMLOG® Vario SR components for bar restorations:

- Anchorage of implant-supported full dentures for the edentulous maxilla and mandible in combination with 2, 4 or more CAMLOG® implants (with J and K article numbers)

DEVICE DESCRIPTION

CAMLOG® Vario SR Abutments are titanium dental implant abutments for use with the CAMLOG® Dental Implant System. They have an internal connection to the implant, a conical interface with the prosthetic attachment, and are used for single and multi-unit screw-retained, prefabricated restorations. They are appropriate for supporting laboratory cast frameworks as well as laser-welded bar constructions and have dedicated prosthetic components.

EQUIVALENCE TO MARKETED DEVICE

Altatec GmbH demonstrated that, for the purposes of FDA's regulation of medical devices CAMLOG® Vario SR Abutments are substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

- Nobel Biocare USA LLC, Multi-Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems, cleared under K061477;
- Nobel Biocare USA LLC, Procera Titanium Abutment for Astra Tech and Camlog Implant Systems, cleared under K061478;
- Nobel Biocare USA LLC, Procera® Implant Bridge, cleared under K043042;
- Nobel Biocare USA LLC, Procera® Abutment Brånemark, cleared under K042658;
- Thommen Medical AG, SPI® VARIOmulti Abutment, cleared under K072856;
- Thommen Medical AG, SPI® VARIOmulti Angled Abutment, cleared under K090153; and
- Thommen Medical AG, SPI® VARIOmulti Angled Abutment, cleared under K101798.

TESTING

Mechanical testing was performed according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* to ensure that the strength of the CAMLOG Vario SR Abutments in conjunction with CAMLOG implants are appropriate for its intended use. Results of fatigue testing confirmed the strength of the system.
Overall, CAMLOG® Vario SR Abutments have 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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

JAN 10 2011

Re: K103252
Trade/Device Name: CAMLOG® Vario SR Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 3, 2011
Received: January 4, 2011

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: K103252

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Device Name: CAMLOG® Vario SR Abutments

Indications for Use:

CAMLOG® Vario SR components for crown and bridge restorations:

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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)

Page 1 of __

Susan Runner

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

510(k) Number: K103252