FEB 17 2006

K051636

510(k) SUMMARY
CAMLOG Endosseous Dental Implant Abutments, Healing Caps and Accessories

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

Date Prepared: February 17, 2006

A. Submitter's Name, Address, Phone and Fax Number

1. Manufacturer of the subject devices

Altatec GmbH
Maybachstrabe 5
Wimsheim, Germany 71299
Phone 011-49-7044-9445-503
Fax 011-49-7044-9445-563
Registration No. 9613866

2. Name of Contact Person

Tina Steffanie-Oak
Senior Regulatory Affairs Specialist
Camlog U.S.A.
520 South Rock Blvd.
Reno, NV 89502
Phone 631-843-5753
Facsimile 631-843-5557
Registration No. 3004575151

B. Device Name, Common Name

1. Device Names

CAMLOG Dental Implant Abutments, Healing Caps, and Accessories

2. Common/Usual Name

Endosseous Dental Implant Abutments, Healing Caps and Accessories

3. Classification Name:

Class II Device, Endosseous Dental Implant Abutments, NHA

C. Predicate Devices:

Healing Caps:

Device Name	Manufacturer	510(k) No.
Straumann Dental Implant System - Healing caps	Institut Straumann AG	Unknown
Replace Select Implant System - Healing abutments	Nobel Biocare	Unknown

Ball Abutments:

Device Name	Manufacturer	510(k) No.
Straumann Dental Implant System - Retentive anchors	Institut Straumann AG	Unknown
Replace Select Implant System - O-Ring abutments	Nobel Biocare	Unknown

Bar Abutments:

Device Name	Manufacturer	510(k) No.
Straumann Dental Implant System - Screw retained abutments	Institut Straumann AG	Unknown
Replace Select Implant System - PME-Abutments	Nobel Biocare	Unknown

Healing Caps for Bar Abutments:

Device Name	Manufacturer	510(k) No.
Healing Cap Item No. 2290	Nobel Biocare	Unknown

Bases and Gold Coping for Bar Abutments:

Device Name	Manufacturer	510(k) No.
RN synOcta Gold Cap Item No. 048.632	Institut Straumann AG	Unknown
PME Coping, Gold Item No. 2149	Nobel Biocare	Unknown

D. Description of the Devices

1. Device Description

The following list of products are used solely in combination with the implantation of CAMLOG dental implants.

Healing Caps – Cylindrical, Wide Body, Bottleneck
Healing caps of specific diameters and shapes are fixated on the implants to displace the gingiva from the space above the implant during the implant healing time and serve for proper gingiva shaping. They are offered in three different shapes; cylindrical, wide body and bottleneck and are available in diameters of 3.3, 3.8, 4.3, 5.0 and 6.0mm. The cylindrical and wide body healing caps are available in Gingival Heights (GH) of 2.0, 4.0 and 6.0mm. The bottleneck healing cap is available in two Gingival Heights of 4.0 and 6.0mm.

Healing Caps for Bar Abutment
This healing cap is connected to the bar abutment and is intended to form the gingival shape similar to the healing caps described above. There are two healing caps for use with the bar abutment, which are made of TiAl6V4. Both have an overall height of 3.65mm, but differ in the base diameter of 4.30 or 6.0mm measured at the outer tube wall.

Ball Abutment
Ball abutments are used for implant-retained mucosa-supported restorations, such as dentures. The ball abutment technique is used on Camlog implants in the maxilla or mandible. When using the ball abutment, the angle of the implant axes must not be more than 10°. Ball abutments with the following diameters are available: 3.3, 3.8, 4.3 and 5.0mm. The male part for each diameter is available in protrusion heights of 1.5, 3.0 and 4.5mm. There are a total of 12 different size ball abutment systems being offered by Altatec.

Bar Abutment
Camlog bar abutments serve to support custom-milled or prefabricated bars to which an overdenture is attached. The bar abutment technique is used on Camlog implants in the maxilla or mandible. The bar abutments are available in various diameters, which include 3.3, 3.8, 4.3, 5.0 and 6.0mm. Each diameter is available in three different protrusion heights of 0.5, 2.0 and 4.0mm. There are a total of 15 different sizes that will be offered for sale.

Bases for Bar Abutment (Solderable, Laser-Welded, Cementable)
The purpose of each specific base is to have a base adapted in geometry and materials selection to each of the following processes: soldering, laser-welding, and cementing. The selection of a specific processing method is made by the dental laboratory.

Gold Coping for Bar Abutment Cast-on
The purpose of the specific gold coping is to have a base adapted in geometry and materials selection to the casting process. The selection of a specific processing method is made by the dental laboratory. We are offering two gold copings for bar abutment cast-on of different sizes, which are compatible to the bar abutments of 3.3, 3.8 and 4.3mm diameter or of 5.0 and 6.0mm diameter.

Prosthetic Screw for Bar Abutment
There are two prosthetic screws for bar abutment, both 5.5 mm long. They vary by diameter (2.10 and 2.50mm) of the cylindrical shank and by the size of the thread (M1.6 and M2). The screws serve to fix the bases or the gold coping to the bar abutment.

Screw for Bar Abutment
There are two screws for bar abutment. Both screws are 20.5 mm long. They vary by diameter (2.1 and 2.5mm) of the cylindrical shank and by the size of their threads (M1.6 and M2).The thread serves to guide and stabilize the impression post through the hollow core of which the screw is directed.

2. Design

The CAMLOG Dental Implant Abutments, Healing Caps, and Accessories have been designed, manufactured and tested in compliance with FDA's Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004.

3. Materials

a. The Healing Caps are made of TiAl6V4.
b. The Female part of the Ball Abutment is made of titanium grade 4, and noble metal alloy Elitor®. The Male part is made of TiAl6V4.
c. The Bar Abutments are made of TiAl6V4.
d. The Solderable Bases are made of noble metal alloy Elunor® WP. Cementable Bases is made of TiAl6V4 and the Laser-Weldable Bases are made of Titanium Grade 4 .
e. The Gold Copings are made of the castable noble metal alloy Cerunor®. The burn-out sleeves are made of POM.
f. The Prosthetic Screws for Bar Abutment are made of TiAl6V4.
g. The Screws for Bar Abutment are made of stainless steel.

4. Intended Use

CAMLOG implants are used to support dental prostheses in the upper and lower jaws.
They may be used for functional and aesthetic oral restoration of partially edentulous and edentulous jaws using crowns, bridges, partial or complete prostheses, which are connected to CAMLOG implants using suitable components.

CAMLOG Ball Abutments support implant retained mucosa supported overdentures.

CAMLOG Bar Abutments (including bases) support custom milled or prefabricated bars for overdentures.

Diameters	4.3 and 6 mm	unknown
Height	3.65 mm	unknown
Material	Titanium Alloy	Titanium Alloy
Reprocessing Method	Steam Sterilization	Disinfection
Compatibility with Dental Implants	Compatible only with CAMLOG Implant System	Compatible only with Replace Select Dental Implant System from Nobel Biocare

Comparison Table for Healing Caps

	Subject Device	Predicate Device	Predicate Device
Item	Healing Cap	Healing Cap	Healing Cap
Item Number(s)	J2010.3340 J2010.3360 J2010.3840 J2010.3860 J2010.4340 J2010.4360 J2010.5040 J2010.5060 J2010.6040 J2010.6060 J2013.3320 J2013.3340 J2013.3360 J2013.3820 J2013.3840 J2013.3860 J2013.4320 J2013.4340 J2013.4360 J2013.5020 J2013.5040 J2013.5060 J2013.6020 J2013.6040 J2013.6060 J2015.3320 J2015.3340 J2015.3360 J2015.3820 J2015.3840 J2015.3860 J2015.4320 J2015.4340 J2015.4360 J2015.5020 J2015.5040 J2015.5060 J2015.6020	048..033 048.034 048.037	61019 61020 61021 61022 61023 61024 61025 61026 61027 61028 61029 61030 61031 61033 61034 61035 61036 61037 61038 61039 61040 61041 61042 61043 61044 61045

	J2015.6040 J2015.6060		
Manufacturer	Altatec	Institut Straumann AG	Nobel Biocare
510K#	Part of this submission	Unknown	Unknown
Intended Use	CAMLOG Healing Caps (Cylindrical, Wide Body, Bottleneck) displace the gingiva from the space above the CAMLOG implant or bar abutment during the CAMLOG implant healing time and serve for proper gingiva shaping.	Same	Same
Diameters	3.3, 3.8, 4.3, 5 and 6 mm	3.3, 4.1 and 4.8	3.5, 4.3, 5.0 and 6.0 mm
Gingival Heights	2, 4 and 6 mm	2, 3 and 4.5 mm	3, 5 and 7 mm
Shapes	Cylindrical, Wide Body, and Bottleneck	Cylindric	Cylindric
Material	Titanium Alloy	Titanium	Titanium Alloy
Sterilization Method	Gamma Irradiation	Unknown	Unknown
Compatibility with Dental Implants	Compatible only with CAMLOG Implant System	Compatible only with Straumann Implant System	Compatible only with Replace Select Dental Implant System from Nobel Biocare

Comparison table for Bases and Gold Coping used with Bar Abutments

	Subject Device	Predicate Device	Predicate Device
Item	Base		
Item Number(s)	Base for bar abutment, Solderable J2258.4300 J2258.6000 Titanium cementable base, passive-fit J2260.3300 J2260.3800 J2260.4300 J2260.5000 J2260.6000 Base for bar abutment, laser-weldable J2262.4300 J2262.6000		

	Gold coping for bar abutment, cast-on with burn-out sleeve J2263.4300 J2263.6000	RN synOcta gold cap 048.632	PME Coping, Gold 2149
Manufacturer	Altatec	Institut Straumann AG	Nobel Biocare
510K#	Part of this submission	Unknown	Unknown
Intended Use	CAMLOG Bar Abutments (including bases) support custor milled or prefabricated bars for overdentures.	Same	Same
Diameters	3.3, 3.8, 4.3, 5.0 and 6.0 mm	3.3, 4.1 and 4.8	3.5, 4.3 and 5.0 mm
Material	Base for bar abutment, Solderable: Elunor®: Au 70.0%, Pt 8.50%, Ag 13.40%, Cu 7.50, Zn 0.50%, Ir 0.10% Titanium cementable base, passive-fit: Titanium Alloy Base for bar abutment, laser-weldable: Titanium Alloy Gold coping for bar abutment, cast-on (Cerunor®) with burn-out sleeve: Cerunor®: Au 60%, Pt 19%, Pd 20%, Ir 1%	RN synOcta gold cap 048.632: Ceramicor: Au 60%, Pt 19%, Pd 20%, Ir 1%	Unknown
Reprocessing Method	Steam Sterilization	unknown	Unknown
Compatibility with Dental Implants	Compatible only with CAMLOG Implant System	Compatible only with Straumann Implant System	Compatible only with Replace Select Dental Implant System from Nobel Biocare

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Altatec GmbH
C/O Ms. Tina Steffanie-Oak
Senior Regulatory Affairs Specialist
Camlog U.S.A.
520 South Rock Boulevard
Reno, Nevada 89502

Re: K051636
Trade/Device Name: Altatec CAMLOG Abutments and Healing Caps
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 12, 2006
Received: January 17, 2006

Dear Mr. Steffanie-Oak:

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.

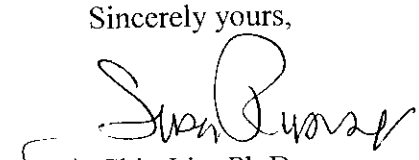
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.
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Enclosure

Indications for Use

510(k) Number (if known): K051636

Device Name: Altatec CAMLOG Abutments and Healing Caps

Indications for Use:

CAMLOG implants are used to support dental prostheses in the upper and lower jaws. They may be used for functional and aesthetic oral restoration of partially edentulous and edentulous jaws using crowns, bridges, partial or complete prostheses, which are connected to CAMLOG implants using suitable components.

CAMLOG Ball Abutments support implant retained mucosa supported overdentures.

CAMLOG Bar Abutments (including bases) support custom milled or prefabricated bars for overdentures.

CAMLOG Healing Caps (Cylindrical, Wide Body, Bottleneck, and for Bar Abutment) displace the gingiva from the space above the CAMLOG implant or bar abutment during the CAMLOG implant healing time and serve for proper gingiva shaping.

Prescription Use YES AND/OR Over-The-Counter Use NO

(Per 21 CFR 801 Subpart D) (Per 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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Susan Runner

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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