JAN 3 2006

K052272

510 (k) Summary

1. Applicant's Name and Address

Straumann Manufacturing (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, Massachusetts 01810
Telephone Number: 800-448-8168
Fax Number: 978-747-0031
Contact Person: Elaine Alan
Regulatory and Clinical Affairs

2. Name of the Device

Trade Name:	Straumann Computer Aided Restoration Service (C.A.R.E.S.) Titanium Abutment
Common Name:	Abutment for endosseous implant
Classification Name:	Accessory to dental implant, 21 CFR 872.3640

3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

Straumann's synOcta Meso Abutment (K033243)

4. Description of the Device

The Straumann Dental Implant System is an integrated system of endosseous dental implants designed to support prosthetic restorations (crowns, bridges, overdentures). The system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments. The subject device, the Straumann C.A.R.E.S. Titanium Abutment, is designed to be custom modified for a particular patient, then inserted into the implant with a basal screw. The titanium abutment provides support for a prosthetic reconstruction, such as a crown.

The Straumann C.A.R.E.S. Titanium abutment is intended for cemented restorations and can be customized to meet high anatomical and esthetic demands. The esthetic properties of the Straumann C.A.R.E.S. Titanium Abutment are designed to create a natural appearance of the soft tissue margin as well as excellent results for crown restoration.

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5. Intended Use of the Device

The Straumann C.A.R.E.S. Titanium Abutment is a device that provides support for cement-retained prosthetic reconstruction, such as a crown. The Straumann C.A.R.E.S. Titanium Abutment is of particular interest in the anterior, canine, and premolar regions where there are high esthetic demands, will be uniquely customized for an individual then placed into the dental implant.

6. Basis for Substantial Equivalence

The Straumann C.A.R.E.S. Titanium Abutment is substantially equivalent to previously cleared meso titanium abutments intended to be used with endosseous dental implants. The design of the subject abutment is very similar to the previously cleared Straumann synOcta Meso Abutment (K033243). Technological characteristics of the device, including material composition, principles of operation, and basic design are identical to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 2006

Ms. Elaine Alan
Regulatory Affairs
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

Re: K052272
Trade/Device Name: Straumann C.A.R.E.S. Titanium Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: NHA
Dated: December 20, 2005
Received: December 21, 2005

Dear Ms. Alan:

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.

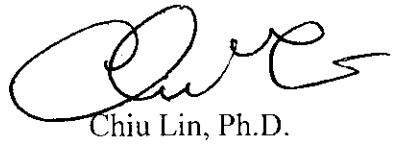
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K052272

Indications for Use

510(k) Number (if known): K

Device Name: Straumann C.A.R.E.S. Titanium Abutment

Indications for Use:

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann C.A.R.E.S. Titanium Abutment is indicated for cemented restorations. The abutment can be used in single tooth replacements and multiple tooth restorations.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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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