K061277

APR 12 2007

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 Affairs Specialist
Regulatory and Clinical Affairs

2. **Name of the Device**

Trade Name: Straumann Computer Aided Restoration Service (C.A.R.E.S.) Ceramic Coping
Common Name: Abutment for endosseous implant
Classification Name: Accessory to dental implant
21 CFR 872.3630

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

Straumann C.A.R.E.S. Titanium Abutment, K052272
Straumann's synOcta® Meso Abutment, K033243
Vident Ceramic Hextop Abutment and synOcta® In-Ceram Coping, K012473
ITI 1.5 mm synOcta Abutment, K022859 and
synOcta Abutments and Prosthetic Accessories, K990342

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. Ceramic Coping, is designed to be custom modified for a particular patient, the coping is fixed to a synOcta® 1.5 abutment which is then fixed to the implant. The ceramic coping provides support for prosthetic reconstructions, such as crowns or bridges.

The Straumann C.A.R.E.S. Ceramic Coping 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. Ceramic Coping are designed to create a

natural appearance of the soft tissue margin as well as excellent results for crown restoration.

5. **Intended Use of the Device**

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

6. **Basis for Substantial Equivalence**

The Straumann C.A.R.E.S. Ceramic Coping is substantially equivalent to the previously cleared predicate devices intended to be used with endosseous dental implants. The design of the subject coping is very similar and the indications for use are identical to the previously cleared copings in the ITI 1.5 mm synOcta Abutment, K022859 and synOcta Abutments and Prosthetic Accessories, K990342. Straumann C.A.R.E.S. Titanium Abutment K052272 and 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 Vident Ceramic Hextop Abutment and synOcta® In-Ceram Coping, K012473. The C.A.R.E.S. Ceramic Coping uses the same software and milling process as the predicate Straumann C.A.R.E.S. Titanium Abutment, K052272.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2007

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

Re: K061277
Trade/Device Name: Straumann C.A.R.E.S. Ceramic Coping
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 19, 2007
Received: March 20, 2007

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.

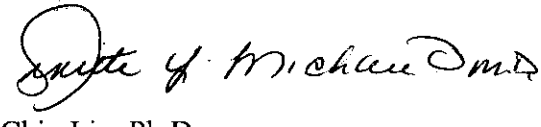
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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): K061277

Device Name: Straumann C.A.R.E.S. Ceramic Coping

Indications for Use:

Copings are intended to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann C.A.R.E.S. Ceramic Coping is indicated for cemented restorations. The coping can be used in single tooth replacements and multiple tooth restorations.

Prescription Use ✓ 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)

Susan Runner

...n of Anesthesiology, General Hospital,
...ction Control, Dental Devices

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