

K080239

Section I
510(k) SUMMARY

APR 30 2008

1. Applicant's Name and Address

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 978-747-2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Affairs Specialist
Date of Submission: January 30, 2008

2. Name of the Device

Trade Name: P.004 RC/NC Bar and Bridge Abutments Line
Common Name: Abutment, Dental, Endosseous implants
Classification Name: Abutment, Dental, Endosseous implants
Regulation Number: 21 CFR 872.3630

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

Straumann Octa Abutment, K894844
Straumann synOcta Abutment, K994119
Temporary Copings, K894844
ITI Protective Healing Caps, K962023, K051717
RN synOcta® Gold Copings for Bridges, K022859
RN synOcta® Gold Copings for Bars, K894844
RN synOcta® Titanium Copings for Bars, K990342

4. Description of the Device

The Straumann P.004 Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments.

Abutments are placed into dental implants to provide support for prosthetic restorations, copings for bars and bridges are used as a base for bar and bridge constructions, temporary copings support a temporary restoration out of occlusion and protective caps protect the abutment during the healing phase.

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5. Intended Use of the Device

Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations. The subject abutments are for permanent screw-retained bridges and bar-retained implant-borne dentures. Permanent copings are intended to serve as a base for multi-unit bar or bridge restorations. Temporary Copings are intended to serve as a base for temporary restorations for up to 6 month. Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.

6. Technological Characteristics

The proposed Bar and Bridge Abutments, Permanent and Temporary Copings and Protective Caps are substantially equivalent to the currently cleared devices. The intended use is **identical** to the predicate devices. The proposed devices have the same material composition, basic design and fundamental operating principles to the currently cleared devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2008

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

Re: K080239
Trade/Device Name: P.004 RC/NC Bar and Bridge Abutment Line
P.004 Abutments
P.004 Protective Caps
P.004 Permanent Bar and Bridge Copings
P.004 Temporary Copings
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 11, 2008
Received: April 21, 2008

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

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INDICATIONS FOR USE STATEMENT

Device Name: P.004 Abutments

Indications for Use:

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures. The subject abutments are for permanent screw-retained bridges and bar-retained implant-borne dentures.

Device Name: P.004 Protective Caps

Indications for Use:

Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.

Device Name: P.004 Permanent Bar and Bridge Copings

Indications for Use:

Copings are intended to serve as a base for multi-unit bar or bridge restorations.

Device Name: P.004 Temporary Copings

Indications for Use:

Temporary Copings are intended to serve as a base for temporary restorations for up to 6 months.

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)

Sharon Powers

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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