

SEP 26 2007

Section I  
510(k) Summary

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**1. Applicant's Name and Address**

Straumann US (on behalf of Institut Straumann AG)  
60 Minuteman Rd.  
Andover, MA 01810  
Telephone Number: 800-448-8168, ext 2507  
Fax Number: 978-747-0023  
Contact Person: Paige Sweeney  
Manager, Regulatory Affairs  
Date of Submission: July 11, 2007

**2. Name of the Device**

Trade Name: P.004 RC/NC Gold Abutment for Bars  
P.004 RC/NC Titanium Abutment for Bars  
Common Name: Abutment, Dental, Endosseous implants  
Classification Name: Abutment, Dental, Endosseous implants  
Regulation Number: §872.3630

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

Straumann P.004 Dental Implants, K062129  
RN synOcta<sup>®</sup> Gold Coping, K990342  
RN synOcta<sup>®</sup> Titanium Coping, K990342  
RN Abutment for Bars, K894844

**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.

## 5. Intended Use of the Device

Both the **P.004 RC/NC Gold Abutment for Bars and RC/NC Titanium Abutment for Bars** are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.

## 6. Technological Characteristics

The proposed abutments are substantially equivalent to the currently marketed devices. The intended use is **identical** to the predicate devices. The proposed abutment has the same material composition, basic design and fundamental operating principles to the currently marketed devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Paige Sweeney  
Manager, Regulatory Affairs  
Straumann USA  
60 Minuteman Road  
Andover, Massachusetts 01810

SEP 26 2007

Re: K071919

Trade/Device Name: P.004 RC/NC Gold and Titanium Abutment for Bars  
Regulation Number: 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: July 11, 2007  
Received: July 12, 2007

Dear Ms. Sweeney:

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

K071919

### Indications for Use Statement

Device Name: P.004 RC/NC Gold and Titanium Abutment for Bars

Indications for Use:

Both the **P.004 RC/NC Gold Abutment for Bars** and **RC/NC Titanium Abutment for Bars** are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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