K070549

Section I
510(k) SUMMARY

AUG 31 2007

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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 2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Affairs Specialist
Date of Submission: February 23, 2007

2. **Name of the Device**

Trade Name: P.004 RC Gold Abutment
Common Name: Abutment, Dental, Endosseous implants
Classification Name: Abutment, Dental, Endosseous implants
21 CFR 872.3640

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

Straumann P.004 Dental Implants, K062129
synOcta Gold Abutment, K041295

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. The devices covered in this submission are abutments.

The basal portion of the abutment has 4 protrusions diametrically opposed that engage in the 4 grooves of the P.004 implant. The abutment is seated in the implant with a screw which is mounted in the basal portion of the abutment. The abutment is used for cemented and screw-retained restorations.

5. **Intended Use of the Device**

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges or overdentures.

6. Technological Characteristics

The proposed abutment is 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Institut Straumann AG
C/O Ms. Elaine Alan
Regulatory Affairs Specialist
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

AUG 3 1 2007

Re: K070549
Trade/Device Name: P.004 Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 23, 2007
Received: August 24, 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 (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

K070549

INDICATIONS FOR USE STATEMENT

Device Name: P.004 Abutment

Indications for Use:

Abutments 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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