

SEP 20 2007

**Section K**  
**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 2513  
Fax Number: 978-747-0023  
Contact Person: Elaine Alan  
Regulatory Affairs Specialist  
Date of Submission: February 9, 2007

**2. Name of the Devices**

Trade Name: RC Temporary Abutments  
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<sup>®</sup> Temporary Meso Abutment, K051717  
P.004 RC Meso Abutment, K062129

**4. Description of the Device**

The Straumann P.004 Dental Implant System is an integrated system of endosseous bone level 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 temporary abutments.

The basal portion of the abutments has 4 protrusions diametrically opposed that engage in the 4 grooves of the P.004 implant. The abutments are 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. Healing abutments protect the inner configuration of the abutment and contours the soft tissue during the healing phase.

**5. Intended Use of the Device**

The RC Temporary Abutment is intended for use with the P.004 dental implant for temporary restoration of single crowns and bridges in the anterior and posterior region for use up to six months.

Healing abutments, often referred to as healing caps, are intended to be used with the P.004 dental implant to protect the inner configuration of the implant during the healing process and maintain, stabilize and form the soft tissue during this phase.

**6. Technological Characteristics**

The proposed abutments are substantially equivalent to the currently marketed devices. The intended use and materials are **identical** to the predicate devices. The proposed abutments have the same 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

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

SEP 20 2007

Re: K070478

Trade/Device Name: P.004 RC Temporary Abutment,  
P.004 Healing Abutment, customizable (cap)

Regulation Number: 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II

Product Code: NHA

Dated: August 21, 2007

Received: August 22, 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.

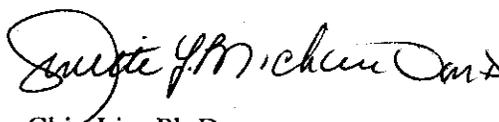
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

A handwritten signature in black ink, appearing to read "Chiu Lin", is written over a faint, larger version of the typed name "Chiu Lin, Ph.D.".

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 STATEMENT

Indications for Use: KO70478

Device Name

**P.004 RC Temporary Abutment** is indicated for use in Straumann P.004 RC Bone Level implants for temporary restorations of single crowns and bridges for up to six months.

Device Name

**P.004 Healing Abutment, customizable (cap)** is indicated for use in Straumann P.004 RC Bone Level implants to protect the inner configuration of the implant during the healing process. Maintains, stabilizes and forms the soft tissue and should be placed out of occlusion for up to six 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)

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Susan P. Rosen  
(Official Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: KO70478