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K071585

Section H
**510(k) Summary**

JUL 11 2007

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

Straumann USA (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

2. **Name of the Device**

| | |
|---|---|
| Trade Name: | NC Healing Abutments, NC Closure Screws |
| Common Name: | Abutment, Dental, Endosseous implants |
| Classification Name: | Abutment, Dental, Endosseous implants<br>§21 CFR 872.3630 |

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

P.004 RC Healing Abutments, K062129
P.004 RC Closure Screws, K062129

4. **Description of the Device**

The Straumann 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 device covered in this submission is healing abutments and closure screws.

Healing abutments and closure screws are used to protect the inner configuration of the implant and to maintain, stabilize and form the soft tissue. Healing Abutments have a secondary function to maintain, stabilize and form the soft tissue during the healing process

5. **Intended Use of the Device**

P.004 Healing Abutments and P.004 Closure Screws are intended for use with the Straumann P.004 Bone Level Implant system to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

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## 6. Basis for Substantial Equivalence

The modified NC Healing Abutments and Closure Screws are substantially equivalent to the currently marketed RC Healing Abutments and closure screws. The intended use is identical to the predicate devices. The proposed abutments and closure screws have 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

JUL 11 2007

Ms. Elaine Alan
Regulatory Affairs Specialist
Straumann USA (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, Massachusetts 01810

Re: K071585
Trade/Device Name: P.004 Healing Abutments and Closure Screws
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 8, 2007
Received: June 11, 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

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**Indications for Use Statement**

Device Name: P.004 Healing Abutments and Closure Screws

Indications for Use:

P.004 Healing Abutments and Closure Screws are intended for use with the Straumann P.004 Bone Level Implant system to protect the inner configuration of the implant. Healing Abutments have a secondary function to maintain, stabilize and form the soft tissue during the healing process.

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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Kim Hurley for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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