K070744

SECTION I
510(k) Summary

JUN 29 2007

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

Straumann USA (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Telephone Number:	978-747-2513
Fax Number:	978-747-0023
Contact Person:	Elaine Alan Regulatory Affairs Specialist
Date of Submission:	March 15, 2007

2. **Name of the Device**

Trade Name:	Narrow Neck Temporary Coping
Common Name:	Accessory to Endosseous Dental Implant
Classification Name:	Accessory to Endosseous Dental Implant 21 CFR 872.3640

3. **Legally Marketed Device to which Equivalence is Claimed (Predicate Device)**
K032498, Titanium Coping for Anterior Implant
RN synOcta® Temporary Meso Abutment, K051717

4. **Description of the Device**
The Straumann 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 a temporary coping.

The Straumann Narrow Neck Temporary Coping is a coping intended to serve as a base for temporary restorations. The temporary coping is for use on the Straumann Standard Plus Ø3.3mm Narrow Neck Implant.

5. **Intended Use of the Device**
The Narrow Neck Temporary Coping acts as a basis for the fabrication of individual temporary restorations and small cemented temporary bridges on Straumann Standard Plus Implants Ø3.3mm Narrow Neck for use up to six months.

6. **Basis for Substantial Equivalence**

The proposed coping is substantially equivalent to the previously cleared Titanium Coping for Anterior Implant, K032498, and the RN SynOcta® Temporary Meso Abutment, K051717. The proposed device is substantially equivalent in intended use, operating principle and basic design and is made of the same materials as the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

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

Re: K070744
Trade/Device Name: Narrow Neck Temporary Coping
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 7, 2007
Received: June 8, 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.

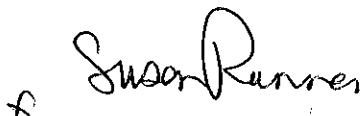
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for 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

510(k) Number (if known): K070744

Device Name: Narrow Neck Temporary Coping

Indications for Use:

The Narrow Neck Temporary Coping acts as a basis for the fabrication of individual temporary restorations and small cemented temporary bridges on Straumann Standard Plus Implants Ø3.3mm Narrow Neck for use 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)

Susan Runyon

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

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