JUL 2 3 2004

K041070

ATTACHMENT 1 - 510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

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

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert
Director, Regulatory Affairs

2. **Name of the Device**

Proposed Trade Name: Straumann Temporary Coping
Common Name: Temporary coping
Classification Name: Accessory to Dental Implant Abutment, NHA

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

Manufacturer	Device	510(k)
Simplified Implant Systems	Universal Dental Coping	K010467
Centerpulse Dental	Hex-Lock Temporary Abutment	K014050
Friadent	ProTect Abutment	Unknown
Lifecore	COC Abutment Temporary Cap	Unknown

4. **Description of the Device and Intended Use**

The Straumann Temporary Coping is a coping intended to serve as a base for a temporary restoration. The temporary coping fits over the Straumann solid abutments and has radial projections that facilitate the retention of added acrylic or composite materials to form a temporary restoration.

5. **Basis for Substantial Equivalence**

The Straumann Temporary Coping is substantially equivalent to the predicate devices since it has a similar design and the same intended use. Like all of the predicate devices, the subject device functions as a base for a temporary restoration. Acrylic or composite material is added over the coping to form the temporary restoration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2004

Ms. Linda Jalbert
Vice President, Regulatory & Clinical Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K041070
Trade/Device Name: Straumann Temporary Coping
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: NHA
Dated: April 23, 2004
Received: April 26, 2004

Dear Ms. Jalbert:

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.

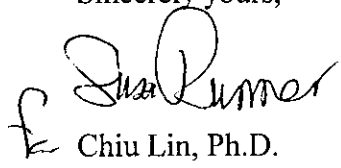
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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

K041070

Indications for Use

510(k) Number (if known):

Device Name: Temporary Coping

Indications For Use:

The Straumann Temporary Coping is a coping intended to serve as a base for a temporary restoration.

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

510(k) Number K041070