MAY - 3 2004

K040646

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 Granules
Common Name: Synthetic Bone Graft Substitute
Classification Name: LYC
Bone Grafting Material, Synthetic

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

Manufacturer	Device	510(k)	Date Cleared
Interpore Cross International	Pro-Osteon® 500R Resorbable Bone Graft Filler	K990131	3/2/1999
Medtronic Sofamor Danek	Biphasic Calcium Phosphate Bone Void Filler	K010701	6/5/2001
Geistlich-Pharma	Bio-Oss® Anorganic Bovine Bone	K970321	9/15/1998
Bio-Interfaces, Inc.	Bii-GRAFT™ (Bioresorbable Calcium Phosphate)	K960164	4/10/1996
Biomatlante	MBCP	K032268	12/11/2003
IsoTiss NV	OsSatura BCP Bone Void Filler	K030131	05/20/2003

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

Straumann Granules are a synthetic resorbable bone graft material made of medical grade beta tricalcium phosphate and medical grade hydroxylapatite. Straumann Granules are indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting. Straumann Granules

provide a bone void filler that is resorbed and replaced with bone during the healing process.

5. Basis for Substantial Equivalence

The Straumann Granules are substantially equivalent based on similar material characteristics and the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Institut Straumann AG
C/O Ms. Linda Jalbert
Director, Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K040646
Trade/Device Name: Straumann Granules
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LYC
Dated: March 10, 2004
Received: March 11, 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

K040646

Indications for Use

510(k) Number (if known):

Device Name: Straumann Granules

Indications For Use:

Straumann Granules are indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting.

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)

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

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