K050515

APR 5 2005

ATTACHMENT 7

510(k) Summary

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
Vice President, Regulatory & Clinical Affairs

2. Name of the Device

Trade Name:	Straumann Bone Block Fixation Set
Common Name:	Bone Block Fixation Set
Classification Name:	Bone Block Fixation Set 21 CFR 872.4880

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

Guided Bone Regeneration System (K011698)

4. Description of the Device

Straumann Bone Block Fixation includes a cassette, instruments, and screws that are slight modifications of ones previously cleared by FDA under K011698. Modification to the instruments and screws are in dimensions only.

5. Intended Use of the Device

Like the predicate device, the Straumann Bone Block Fixation Set is intended for stabilizing and fixating bone grafts and bone filling materials for the regeneration of bone in the oral cavity.

6. Basis for Substantial Equivalence

The Straumann Bone Block Fixation Set is substantially equivalent to the previously cleared Straumann Guided Bone Regeneration (GBR) System. The intended use is the same. The screws and instruments are similar, and in some cases identical, to the previously cleared GBR System screws and instruments. The screws are composed of CP Grade 4 titanium, which is identical to the previously cleared GBR System screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2005

Ms. Linda Jalbert
Vice President, Regulatory and Clinical Affairs
Straumann USA, Incorporated
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K050515
Trade/Device Name: Bone Block Fixation Set
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: March 18, 2005
Received: March 21, 2005

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 (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,

Anthony D. Watson 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): K050515

Device Name: Bone Block Fixation Set

Indications for Use:

Straumann Bone Block Fixation is used to stabilize and fixate bone grafts and bone filling materials for the regeneration of bone in the oral cavity. The bone grafting fixation technique can make it possible for the placement of dental implants in previously unsuitable sites.

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

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