APR 3 0 2004

K040469

ATTACHMENT 8

510(k) Summary

1. Applicant's Name and Address

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 024511
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Carolyn Bitetti
Associate Director, Regulatory Affairs

2. Name of the Device

Trade Name:	Straumann Ortho implant
Common Name:	Endosseous dental implants
Classification Name:	Endosseous dental implants 21 CFR 872.3640

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

Straumann Ortho System (K982509)

4. Description of the Device

The Ortho implant is a solid, one-piece, threaded, self-tapping design made from CP Grade 4 titanium. It has a sand-blasted, acid etched (SLA) rough surface on the endossous portion of the implant. The transmucosal section of the implant has a smooth machined surface to allow for the attachment of epithelial tissue. The coronal portion of the implant is internally threaded and has a hex head.

5. Indications for Use

The Ortho implant of the Straumann Ortho system is an endosseous implant intended for placement in the mid-sagittal area of the hard palate or in retromolar positions. Its purpose is to provide a fixed anchorage point for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It is used temporarily and is intended to be removed after orthodontic treatment has been completed.

6. Basis for Substantial Equivalence

The subject Ortho implants are substantially equivalent in intended use to the currently marketed Straumann Ortho implants.

The subject Straumann Ortho implants have the same design as the previously cleared Straumann Ortho implants. There has been no change in material, surface treatment, design, or operating principle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2007

Ms. Carolyn Bitetti
Associate Director, Regulatory Affairs
The Straumann Company
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K040469
Trade/Device Name: The Straumann Ortho Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: OAT
Dated: February 20, 2004
Received: February 24, 2004

Dear Ms. Bitetti:

This letter corrects our substantially equivalent letter of April 30, 2004.

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 (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 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 continue 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-__ (see http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu S. Lin, PhD
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 (K982509): K040469

Device Name: Straumann Ortho Implant

Indications for Use:

The Ortho implant of the Straumann Ortho system is an endosseous implant intended for placement in the mid-sagittal or paramedian area of the hard palate or in retromolar positions. Its purpose is to provide a fixed anchorage point for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It is used temporarily and is intended to be removed after orthodontic treatment has been completed.

Ortho implants can be used in adults and juveniles (age 12 and older). In case of patients who have not yet completed skeletal growth (e.g. as shown by radiographic analysis of the hand/wrist), the ortho implant should be placed off the mid-line in the paramedian region of the palate in order to avoid the mid-palatal suture.

Prescription Use ✓ 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)

Robert S Betz DDS for Dr Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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