K060062

510(k) Summary

1. Applicant's Name and Address

Straumann Manufacturing (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 2513
Fax Number: 978-747-0031
Contact Person: Elaine Alan
Regulatory Affairs

FEB 3 2006

2. Name of the Device

Trade Name:	**Straumann Orthosystem**
Common Name:	Orthodontic implants
Classification Name:	Endosseous dental implants 21 CFR 872.3640

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

Straumann Orthosystem, originally cleared under K982509 and K040469
Straumann TE Dental Implants, originally cleared under K012757.

4. Description of the Device

The Straumann Palatal Implant is a modification of the Straumann Ortho Implant. The Palatal Implant is a one piece, threaded self-tapping titanium screw implant with an insertion depth of 4 mm. The design of the Palatal Implant is very similar to the predicate Straumann ortho implants and TE dental implants. The surface of the Palatal implant is the grit blasted, acid etched SLA surface, which is the same as that of the predicate devices. The design of the endosseous part of the palatal implant is the same as the current Straumann TE implants, originally cleared under K012757.

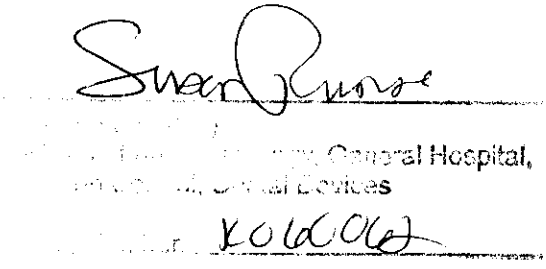
5. Intended Use of the Device

The Palatal Implant is intended to provide fixed anchorage 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 Palatal implant and accessories are substantially equivalent to the previously cleared Straumann Orthosystem and Straumann TE implants. The intended use is identical to the predicate Orthosystem. The Palatal implant is indicated for placement in the mid-sagittal or paramedian area of the hard palate or in retromolar positions to provide a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is intended to be removed after orthodontic treatment has been completed.

The subject Palatal implant has the same material composition and the same surface treatment as previously cleared Straumann implants. In addition, the design of the implant and accessories is similar to, and in some respects identical to, the predicate devices.



Prescription Use ✓
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2007

Institut Straumann AG
C/O Ms. Elaine Alan
Regulatory & Clinical Affairs
Straumann Manufacturing
60 Minuteman Road
Andover, Massachusetts 01810

Re: K060062
Trade/Device Name: Straumann Implant for the Orthosystem
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: OAT
Dated: January 6, 2006
Received: January 9, 2006

Dear Ms. Alan:

This letter corrects our substantially equivalent letter of February 3, 2006.

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.

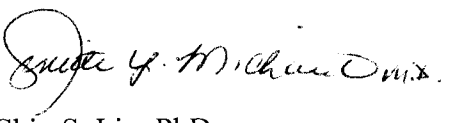
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Device Name:

Straumann Palatal Implant for the Orthosystem

Indications for Use:

The Straumann Palatal implant is 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 the 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.

Palatal 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 palatal implants should be placed off the mid-line in the paramedian region of the palate in order to avoid the mid-palatal suture.

Susan Runyan

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

510(k) Number K060062

Prescription Use ✓
(Per 21 CFR 801.109)