P.1

K062129

510(k) Summary

OCT 20 2006

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: 978-747-0023
Contact Person: Elaine Alan
Regulatory Affairs

2. **Name of the Device**

Trade Name:	P.004 Implants
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)**

ITI Tapered Dental Implant, K012757
ITI Dental Implant System, synOcta Meso Abutment, K033243

4. **Description of the Device**

The P.004 Implant is an addition to the currently distributed Straumann Dental Implant System. The P.004 implant is a solid screw with a SLA (grit blasted then acid etched) or SLActive surface. The implants are composed of Grade 4 commercially pure Titanium and are available in a range of lengths and diameters.

This submission also includes a Titanium Meso abutment and healing caps which are used as accessories to dental implants.

5. **Intended Use of the Device**

The P.004 is intended for immediate, delayed, or conventional placement in the anterior maxillary and/or mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients.

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. Meso abutments are indicated for cemented restorations particularly in esthetic

areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations.

6. **Basis for Substantial Equivalence**

The subject dental implant is substantially equivalent to the previously cleared ITI Tapered Dental Implant. The intended use is identical to the predicate device.

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

The subject Meso abutment is to be used with the P004 implant and has the same intended use and is made of the same material as the previously cleared synOcta Meso Abutment. The design of the subject abutment is substantially equivalent to the previously cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 2 0 2006

Re: K062129
Trade/Device Name: P.004 Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 6, 2006
Received: October 10, 2006

Dear Ms. Alan:

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,

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

K062129

Indications for Use Statement

Device Name: P.004 Implants

Indications for Use:

The P.004 Implants are intended for immediate, delayed or conventional placement in the maxilla and/or mandibular arches to support crowns bridges or overdentures in edentulous or partially edentulous patients.

They are intended for immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used.

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. Meso abutments are indicated for cemented restorations particularly in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations.

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)

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Kevin Mulley for MSE
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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