K033922

JAN - 7 2004

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: Carolyn Bitetti
Assistant Director, Regulatory Affairs

2. Name of the Device

Trade Name:	ITI® DENTAL IMPLANT SYSTEM (Standard PLUS 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 Esthetic PLUS Solid Screw Implants (K983742 and K030007)

4. Description of the Device

The ITI Standard PLUS implants are modifications of the currently distributed ITI Esthetic PLUS implants. The subject implant is a solid screw with an SLA surface (grit blasted then acid etched). The implants are composed of Grade 4 commercially pure titanium and are available in a range of lengths and diameters.

5. Intended Use of the Device

ITI implants are surgically placed in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous

patients. ITI Dental Implants are for single-stage or two-stage surgery. The implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used.

6. Basis for Substantial Equivalence

The subject ITI dental implants are substantially equivalent to the previously cleared ITI Esthetic PLUS implants. The intended use is identical to the predicate device. ITI implants are surgically placed in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. ITI Dental Implants are for single-stage or two-stage surgery. The implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used.

The subject ITI implants have the same material composition and the same surface treatment as previously cleared ITI implants. In addition, the design of the modified implant is almost identical to the previously cleared Esthetic PLUS implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2004

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

Re: K033922
Trade/Device Name: Modification To ITI Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: December 15, 2003
Received: December 18, 2003

Dear Ms. Bitetti:

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

Indications for Use

510(k) Number (if known): K033922

Device Name: Modification to ITI Dental Implant System

Indications for Use:

ITI implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. ITI Dental Implants are for single-stage or two-stage surgery.

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

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)

(Division Sign-Off)
Division of Anesthesiology, Gener...
Infection Contro...

510(k) Number: K033922