K032498

AUG 27 2003

ATTACHMENT 5 - 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
Director, Regulatory Affairs

2. **Name of the Device**

Trade Name: Titanium coping for ITI anterior 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)**

ITI Gold coping for anterior implant (K010921)
SynOcta milling cylinders (K022859)

4. **Description of the Device**

The ITI Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially, or fully edentulous patients. The system consists of a variety of dental implants, abutments, and surgical and prosthetic parts and instruments. The devices covered by this submission are titanium angled copings for the ITI anterior implant.

5. **Intended Use of the Device**

The ITI Dental Implant System is an integrated system of endosseous dental implants which are designed to support prosthetic devices (crowns, bridges, and overdentures) for partially and fully edentulous patients. The system consists of a variety of dental implants, abutments, copings and other surgical and prosthetic parts and instruments.

The device that is the subject of this submission is an angled titanium coping, which is a pre-manufactured component offering a pre-formed inner surface for mating with the dental implant abutment. The outer surface of the coping is adapted to the individual restoration.

6. **Basis for Substantial Equivalence**

The subject devices are substantially equivalent to previously cleared ITI copings. The intended use of the subject coping is identical to the predicate copings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2003

Ms. Linda Jalbert
Director of Regulatory Affairs
Straumann USA
Reservoir Place
1601Trapelo Road
Waltham, Massachusetts 02451

Re: K032498
Trade/Device Name: Titanium Coping for the ITI Anterior Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implants
Regulatory Class: III
Product Code: NHA
Dated: August 8, 2003
Received: August 16, 2003

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 (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,

Susan Runner, DDS, MA
Interim Direction
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032498

Device Name: Titanium coping for the ITI Anterior implant

Indications For Use:

The device that is the subject of this submission is an angled titanium coping, which is a pre-manufactured component offering a pre-formed inner surface for mating with the dental implant abutment. The outer surface of the coping can be adapted to the individual restoration. The coping is angled and is used only with the ITI anterior implant.

Kevin Mulhay for MSN

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032498

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)