

7K984104

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 02451

Telephone Number: 781-890-0001

Fax Number: 781-890-6464

Contact Person: Linda Jalbert, Director of Regulatory Affairs

2. Name of the Device

Trade Name: ITI Dental Implant System®

Common Name: Dental Implant

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

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

ITI Dental Implants (K894595, K971578)

Nobel Biocare Branemark Implants (K925765, K934825)

Implant Innovations Implants (K954347, K960417)

Sterngold Implamed Implants (K981516)

SARGON Dental Implants (K930071)

4. Description of the Device

The All-in-One implants are screw type dental implants made from CP titanium, Grade 4. They are available in various insertion lengths. The implants have the same rough surface as cleared ITI endosseous implants. The transmucosal part has a smooth machined surface to allow for the attachment of epithelial tissue.

5. Intended Use of the Device

The ITI All-in-One Dental Implants are intended to be placed in the maxillary and/or mandibular arch to support prosthetic reconstructions in edentulous or partially edentulous patients.

6. Basis for Substantial Equivalence

The modified ITI dental implants are substantially equivalent to ITI Dental Implants, the Nobel Biocare Branemark implants, Sargon and Implant Innovations Dental Implants in intended use, material and design.

The modified ITI dental implants have the same intended use as the current ITI dental implants, the Nobel Biocare Branemark implants, Sargon and Implant Innovations dental implants.

The modified ITI implants are composed of the same material and have the same surface as the cleared ITI dental implants. In addition, the design of the modified ITI implants is similar to the cleared ITI implants. The implant has a rough surface in contact with bone for osseointegration and a smooth titanium surface in contact with mucosa. The design of the modified implants are also similar to the commercially available Nobel Biocare Branemark, Sterngold Implamed, and Implant Innovations implants.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 13 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K984104
Trade Name: ITI Dental Implant System®
Regulatory Class: III
Product Code: DZE
Dated: February 18, 1999
Received: February 19, 1999

Dear Ms. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

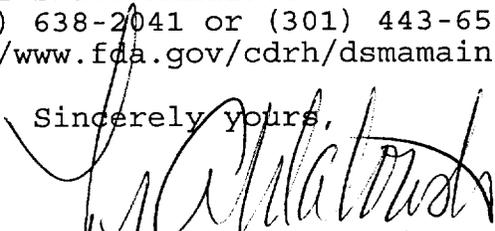
Page 2 - Ms. Jalbert

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page ___ of ___

510(k) Number (if known): K984104

Device Name: ITI One Part Implant

Indications For Use:

ITI One Part octa 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 one-part octa implants are for use in edentulous jaws in conjunction with bar-borne superstructure on 4 implants. If ITI one-part implants are splinted with a bar, they can be loaded immediately.

ITI one-part implants can also be used for indications requiring endosseous implants for functional rehabilitation in regions where an ITI two part implant and an Octa abutment would normally be used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Ruppner

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

510(k) Number K984104

(Optional Format 3-10-98)

Prescription Use
(Per 21 CFR 801.109)