MAR 17 2000

K994119

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: Linda Jalbert, Director of Regulatory Affairs

2. **Name of the Device**

Trade Name:	synOcta® Angled Abutment
Common Name:	Dental Implant Abutment
Classification Name:	Accessories to Endosseous Dental Implant (21 CFR 872.3640)

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

ITI® synOcta® Abutment (K990342)
ITI® Angled Abutment (K962647)
Calcitek Angled Abutment (K number unknown)
Nobel Biocare Angled Abutment (K905434)
Implant Innovations Angled Abutment (K number unknown)

4. **Description of the Device**

The subject device of this 510(k) is the ITI® synOcta® Angled Abutment which is placed into the dental implant to provide support for a prosthetic reconstruction. The angled abutment is used for angulation correction in cases where the angle of placement of the dental implant requires an angled reconstruction for an aesthetic result.

The synOcta® abutment is available in 15° and 20° angles and is made from commercially pure Grade 4 titanium (cold worked) which conforms to ASTM Standard Specification F67. The abutment is provided non-sterile in medical grade heat-sealed packaging.

The basal portion of the modified angled abutment has an 8° conical taper which fits into the coronal portion of the ITI implants. The abutment is held in place with a screw located in the basal portion of the abutment. This screw is composed of titanium alloy. The abutment is manufactured out of a single piece of titanium. The screw and suspension ring are mounted into the basal portion of the abutment. The coronal aspect of the abutment has an occlusal thread for the impression coping and a lateral screwdriver access hole.

5. **Intended Use of the Device**

The synOcta® angled abutment is indicated to be used in cases where the angle of placement of the implant requires an angled reconstruction for an aesthetic result. The abutment can be used to restore both crowns for single tooth replacements and bridges for bound situations.

6. **Basis for Substantial Equivalence**

The ITI® synOcta® angled abutment and accessories are substantially equivalent in intended use, material and design to devices marketed by ITI® (Straumann), Nobel Biocare, Implant Innovations, and Calcitek.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

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

Re: K994119
Trade Name: SynOcta® Angled Abutments
Regulatory Class: III
Product Code: DZE
Dated: December 3, 1999
Received: December 6, 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 (Premarket 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 premarket notification submission does not affect any

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) 594-4690. 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

K994119

Indications for Use Statement

Device Name:

SynOcta® Angled Abutments

Indications for Use:

The synOcta® angled abutments are indicated for use in cases where the placement of the implant requires an angled reconstruction for an aesthetic result. The abutment can be used to restore crowns for single tooth replacements and bridges for bound situations.

The angled abutment is not to be used in conjunction with the ITI 15° angled implant as the total degree of angulation is 30 degrees or above.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994119