K990342

JUL 20 1999

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 Prosthetics®
Common Name: Prosthetic Accessories to Dental Implant
Classification Name: Accessories to Endosseous Dental Implant
(21 CFR 872.3640)

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

ITI Abutments, copings, transfer system components (K894844 and K943720)
Nobel Biocare's prosthetic accessories
Implant Innovations' prosthetic accessories
Friatec's prosthetic accessories

4. **Description of the Device**

The prosthetic accessories to the All-in-One implants include abutments, copings, cylinders, temporary posts, transfer copings, and miscellaneous accessories. These components are composed of titanium, titanium alloy, gold alloy, and plastic (burn-out).

5. **Intended Use of the Device**

ITI Dental Implants are intended to be placed in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in edentulous or partially edentulous patients. The prosthetic accessories to dental implants are used either in the process of fabricating the prosthetic restoration for the implant or as part of the prosthetic restoration.

6. **Basis for Substantial Equivalence**

The modified ITI prosthetic accessories are substantially equivalent in intended use, material and design to prosthetic accessories marketed by ITI (Straumann), Nobel Biocare, Implant Innovations, and Friatec.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

Ms. Linda Jalbert
Director, Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham Massachusetts 02154

Re: K990342
Trade Name: SynOcta Prosthetics®
Regulatory Class: III
Product Code: DZE
Dated: May 28, 1999
Received: June 1, 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 obligation you might have under sections 531 through 542 of 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

Indications for Use Statement

K990342

Device Name:

Prosthetic Accessories to ITI Dental Implants

Indications for Use:

Prosthetic accessories are used in conjunction with ITI dental implants in the prosthetic restoration of the implant. These prosthetic accessories include abutments, copings and cylinders, and transfer system components. Abutments are placed into the dental implants to provide support for prosthetic restorations such as crowns, bridges, and overdentures. Prefabricated copings and cylinders provide a machined or cast inner surface for mating with the abutment and implant, while the outer surface can be adapted to the individual restoration. Transfer system components are used in the process of transferring the situation in the oral cavity to a precise dental model. Protection caps are used to protect the outer configuration of the abutment and to maintain and condition the soft tissues during the prosthetic phase.

Prescription Use ✓
(Per 21 CFR 801.109)

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K990342