NOV 24 1999

K992682

ATTACHMENT 7 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Medartis, GmbH)
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:	MODUS® 2.5 Mandibular Reconstruction System
Common Name:	Craniofacial fixation system
Classification Name:	Multiple component bone fixation metallic appliances (21 CFR 888.3030)

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

MODUS® Titanium Osteosynthesis System (K946165)
Stryker® Leibinger MARX™ TITANIUM Mandibular Bridging Plate System
Synthes® Mandibular Modular Fixation System (K954385)
Synthes – 2.4 Mandibular Fracture Set (K961421)
Stryker® Leibinger TITANIUM Locking Screw Mandibular Reconstruction Plating System

4. **Description of the Device**

The MODUS® 2.5 Mandibular Reconstruction Set is a complete fracture fixation system that includes titanium plates, titanium screws, templates, and accompanying instruments and accessories.

5. **Intended Use of the Device**

The indications for use of the MODUS® 2.5 Reconstruction Set include reconstruction surgery, including bone grafting and bridging defects in the mandible after tumor resection or severe infection. It is also indicated for use in mandibular trauma fractures, e.g. in unstable, comminuted mandibular fractures and bone loss.

6. **Basis for Substantial Equivalence**

The MODUS® 2.5 Reconstruction Set is substantially equivalent to the MODUS® System previously cleared in K946165. The MODUS® 2.5 Reconstruction Set is also substantially equivalent to the Stryker® Leibinger MARX™ TITANIUM Mandibular Bridging Plate System, the Synthes® Mandibular Modular Fixation System and Universal Locking Plate System, and the Stryker® Leibinger TITANIUM Locking Screw Mandibular Reconstruction Plating System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Medartis
c/o Ms. Linda Jalbert
Medartis
Director, Regulatory Affairs
Straumann USA
1601 Trapelo Road
Reservoir Place
Waltham, MA 02451

Re: K992682
Trade Name: MODUS 2.5 Mandibular Reconstruction Set
Regulatory Class: II
Product Code: JEY
Dated: November 9, 1999
Received: November 10, 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

510(k) NUMBER (IF KNOWN): K992682

DEVICE NAME: MODUS® 2.5 Mandibular Reconstruction Set

INDICATIONS FOR USE:

The indications for use of the MODUS® 2.5 Reconstruction Set include use in reconstruction surgery, including bone grafting and bridging defects in the mandible after tumor resection or severe infection. It is also indicated for use in mandibular trauma, e.g. unstable, comminuted mandibular fractures and bone loss.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992682