

NOV 24 1999

K92683

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 Trauma Set
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)**

- KLS Martin – 2.5 Mandibular Fracture Set (K950045)
- W. Lorenz – 2.4 Fracture System
- Synthes – 2.4 Mandibular Fracture Set (K961421)
- Leibinger – CMF Modular Plating System

4. **Description of the Device**

The MODUS® 2.5 Mandibular Trauma 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 MODUS® 2.5 Trauma Set is intended 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 Trauma Set is substantially equivalent in intended use, design, and materials to the MODUS® Titanium Osteosynthesis System previously cleared in K946165, the KLS Martin 2.5 Mandibular Fracture Set, the W. Lorenz 2.4 Fracture System, the Synthes 2.4 Mandibular Fracture Set, and the Leibinger CMF Modular Plating System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 24 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992683
Trade Name: MODUS 2.5 Mandibular Trauma Set
Regulatory Class: II
Product Code: JFY
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.

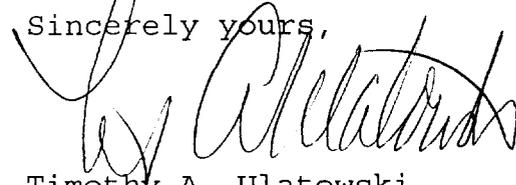
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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): K9921083

DEVICE NAME: MODUS® 2.5 Mandibular Trauma Set

INDICATIONS FOR USE:

The MODUS® 2.5 Trauma Set is intended for use in mandibular trauma fractures, e.g. in 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)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K9921083