

K993862

DEC 29 1999

ATTACHMENT 8 - 510(k) Summary1. **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® Titanium Osteosynthesis System -
Sagittal Split Plate and Slider
Common Name: Craniomaxillofacial Fixation Plates
Classification Name: Bone plate, 21 CFR 872.4760, Class II

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

MODUS® System Plates and Mesh (K946165)
Synthes 2.0 mm Sagittal Split Plates (K981890)
Synthes (MMFS) – Adjustable Sagittal Split Plate (K964328)

4. **Description of the Device**

The MODUS® System sagittal split plate with slider has a U-shaped design. It is available in two configurations, with six or eight screw holes. The plate is composed of CP Grade 1 titanium. The plate has a thickness of 0.7 mm and is available in a range of lengths of 31.65mm to 52.65 mm. The slider is 10 mm in diameter and is composed of Grade 4 CP titanium meeting ASTM F67.

5. **Intended Use of the Device**

The MODUS® Titanium Osteosynthesis System is intended for use in oral, maxillofacial surgery such as: trauma; surgical correction of dentofacial deformities; reconstructive surgery; orthognathic and craniofacial surgery. The MODUS® Sagittal Split Plate with slider is used for stabilization of mandibular bone segments after a sagittal split osteotomy.

6. **Basis for Substantial Equivalence**

The MODUS® Sagittal Split Plate with Slider and Screws are substantially equivalent to previously cleared MODUS® craniofacial plates and mesh, and to Synthes sagittal split-fix plates in terms of intended use, design, and material.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Linda Jalbert
Director, Regulatory Affairs
The Straumann Company
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451

Re: K993862
Trade Name: MODUS® Titanium Osteosynthesis System
Regulatory Class: II
Product Code: JEY
Dated: November 12, 1999
Received: November 15, 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

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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,

Gerald W. Shypps

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

Device Name:

MODUS® Titanium Osteosynthesis System - Sagittal Split Plate and Slider

Indications for Use:

The MODUS® Titanium Osteosynthesis System is intended for use in oral maxillofacial surgery such as: trauma; surgical correction of dentofacial deformities; reconstructive surgery; orthognathic and craniofacial surgery. The Sagittal Split Plate with slider is used for stabilization of mandibular bone segments after a sagittal split osteotomy.

Prescription Use _____ ✓
(Per 21 CFR 801.109)

Angela Blackwell for MSR
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993862