

SEP 17 1999

**ATTACHMENT 8 - 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® System Self-drilling Screws  
 Common Name: Craniomaxillofacial Fixation Plates/ Screws  
 Classification Name: Multiple component bone fixation metallic appliances (21 CFR 888.3030)

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

MODUS System Screws (K946165)  
 Synthes Self-Drilling Maxillofacial Screw (K983485)  
 KLS Martin Drill-Free Screws (K971297)  
 Lorenz Self-Drilling Screw  
 Leibinger Self-Drilling Screw (K970912)  
 TIMESH System Screws (K974107)

**4. Description of the Device**

The MODUS® System Self-drilling Screws are self-tapping self drilling screws for use with the cleared MODUS plates and mesh fixation components. The screws are made from CP titanium, Grade 4 or titanium alloy. The screws are available in lengths ranging from 3 mm to 8 mm and diameters ranging from 1.2 to 2.0 mm.

**5. Intended Use of the Device**

There is no change to the intended use or indications for use of the cleared MODUS system, with the modified Self-drilling screws. The MODUS System is intended for use in the internal fixation in the craniofacial skeleton, secondary to trauma, reconstruction, or surgical correction of dento-facial deformations.

**6. Basis for Substantial Equivalence**

The MODUS Self-drilling Screws are substantially equivalent to the MODUS self tapping screws, Synthes Self-Drilling screws, the KLS Martin Drill-Free Screws, the Lorenz Self-Drilling Screw, the Leibinger Self-Drilling Screw, and the TIMESH System Screws in intended use, material and design.

The MODUS Self-drilling Screws have the same intended use as the predicate devices. Like these predicate devices, the Straumann MODUS Self-drilling Screws are intended to be used for the internal fixation in the craniofacial skeleton, secondary to trauma, reconstruction, or surgical correction of dento-facial deformations.

As are the predicate devices, the MODUS Self-drilling Screws are composed of commercially pure Grade 4 titanium or titanium alloy. In addition, the design of the MODUS Self-drilling Screws is the same as the Synthes Self-Drilling screws, the KLS Martin Drill-Free Screws, the Lorenz Self-Drilling Screw, and the Leibinger Self-Drilling Screw. Like these predicate devices, the MODUS Self-drilling Screws have a tapered thread for self drilling capability.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K992106  
MODUS Self-Drilling Screws  
Regulatory Class: II  
Product Code: HWC  
Dated: June 18, 1999  
Received: June 22, 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.

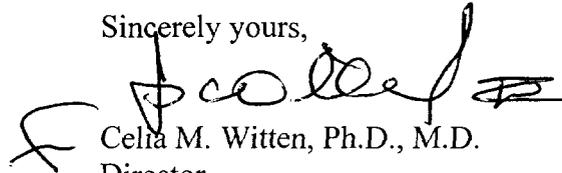
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

Page 2, -Ms. Linda Jalbert

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) 594-4659. 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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K992106

DEVICE NAME: MODUS® System Self-drilling Screws

INDICATIONS FOR USE:

The MODUS System Self-drilling Screws are intended for use in the internal fixation in osteotomies and fractures of the craniofacial skeleton which require positional and functional stability.

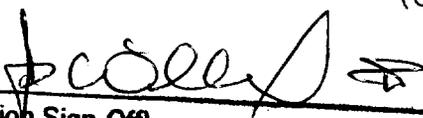
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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K992106