MAY - 5 2005 K050934

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Medartis, Inc. 127 W Street Road, Suite 203 Kennett Square, PA 19348 Telephone (610) 961-6101 FAX (610) 961-6108
Official Contact:	Kate Gehret
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Plate, Bone
Trade/Proprietary Name:	MODUS® Titanium Osteosynthesis System
Common Name:	Bone Plates

ESTABLISHMENT REGISTRATION NUMBER

Medartis, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number has not yet been assigned.

DEVICE CLASSIFICATION

FDA has classified bone plates as Class II devices (21 CFR 872.4760). The product code for bone plates is JEY. This device classification is reviewed by the Dental Products Panel.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards applicable to bone plates have been established by FDA. However, the CP titanium used to manufacture the MODUS® Titanium Osteosynthesis System meets the chemical and mechanical requirements of ASTM F 67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications* and ISO 5832-2 *Implants for surgery – Metallic materials – Part 2: Unalloyed titanium.*

PREDICATE DEVICE INFORMATION

The predicate devices for this modification are from the MODUS® Titanium Osteosynthesis System. Medartis AG, the parent organization of Medartis, Inc. has acquired the rights to the Elekta Instruments, Inc. CMF-Titanium Cranio-Maxillo-Facial Fracture Fixation System, cleared by FDA on May 23, 1995 under K946165, and has marketed it as the MODUS® Titanium Osteosynthesis System. The MODUS System was expanded with the addition of the MODUS® 2.5 Mandibular Trauma Set, cleared by FDA

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on November 24, 1999 under K992683. The MODUS System has now been modified by the addition of new shapes, which are the subject of this Special 510(k).

PACKAGING/LABELING/PRODUCT INFORMATION

The MODUS® Titanium Osteosynthesis System will be packaged and sold non-sterile. The device is not represented to be "pyrogen free." All catalogues will be amended to include the modified devices, consistent with the information shown for existing devices.

INTENDED USE

The MODUS® Titanium Osteosynthesis System is intended for osteotomies and fractures involving any part of the craniofacial skeleton and requiring positional and functional stability. Indications include fixation in the nasoethmoidal, intraorbital, and frontal sinus areas; fixation of comminuted fractures of maxillo-facial and craniofacial areas; tumor surgery for defect bridging; reconstruction of bony structures by means of mesh materials; coverings for burr holes in the skull; trauma of nasal bones; surgical correction of dentofacial deformations; and reconstruction after tumor surgery.

DEVICE DESCRIPTION

The MODUS® Titanium Osteosynthesis System consists of implant plates, implant screws and instruments and is used for the internal fixation of fractures, correction osteotomies, the bridging of load bearing bone segments and distraction in the craniofacial skeleton. This submission includes modifications to the MODUS system plates that enhance clinical effectiveness due to improved strength or anatomical adaptation. All modifications discussed in this submission use previously cleared Medartis titanium screws.

EQUIVALENCE TO MARKETED PRODUCT

The modified implants included in this submission have the following similarities to the predicate:

- have the same intended use,
- use the same operating principle,
- incorporate the same basic design, and
- incorporate the same materials.

In summary, the modified implants described in this submission are, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Medartis, Incorporated
C/O Mr. Floyd G. Larson
President
PaxMed, International
11234 El Camino Real
San Diego, California 92130

Re: K050934
Trade/Device Name: MODUS® Titanium Osteosynthesis System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 11, 2005
Received: March 14, 2005

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

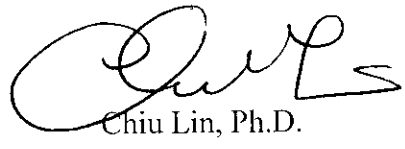
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050934

Device Name: MODUS® Titanium Osteosynthesis System

Indications for Use:

The MODUS® Titanium Osteosynthesis System is intended for osteotomies and fractures involving any part of the craniofacial skeleton and requiring positional and functional stability. Indications include fixation in the nasoethmoidal, intraorbital, and frontal sinus areas; fixation of comminuted fractures of maxillo-facial and craniofacial areas; tumor surgery for defect bridging; reconstruction of bony structures by means of mesh materials; coverings for burr holes in the skull; trauma of nasal bones; surgical correction of dentofacial deformations; and reconstruction after tumor surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for HSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K050934