K071612

1 of 2

510(k) Summary

Medartis AG
MODUS® Trilock® 2.0/2.3/2.5

SEP 11 2007

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Medartis AG Austrasse 24 Basel, CH 4051 Switzerland Telephone +41 61 228 18 18 Fax +41 61 228 18 00
Official Contact:	Kerttu Spiess
Representative/Consultant:	Linda Schulz or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone 1 (858) 792-1235 Fax 1 (858) 792-1236 email: lschulz@paxmed.com or flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	MODUS® Trilock® 2.0/2.3/2.5
Common Name:	Bone plate
Classification Regulations:	21 CFR 872.4760, Class II
Product Codes	JEY

DEVICE CLASSIFICATION PANEL

The Classification Panel for these devices is the Dental Products Panel, and they are reviewed by the Dental Devices Branch

INTENDED USE

The MODUS® TriLock® 2.0/2.3/2.5 is intended for use in the mandible and mid-face region for osteotomies, severe fractures and comminuted fractures. These fractures may include condylar neck fractures, mandibular angle fractures, fractures of the atrophic mandible and fractures of the orbita and zygoma complex. Mandibular reconstruction may be performed with free or vascular bone graft.

2072
K071612

DEVICE DESCRIPTION

MODUS® TriLock® 2.0/2.3/2.5 is a fixation system for use in mandibular and midface trauma and reconstruction. It consists of implant plates and implant screws. Manual surgical instruments, Class I exempt and not a subject of this submission, are included in the system.

The plates of the subject system are the same as plates included in the previously cleared predicate Modus Titanium Osteosynthesis System (K050934), except that the screw holes of the subject system plates are designed to accommodate TriLock Hexadrive® 6 locking screws.

The MODUS® TriLock® 2.0/2.3/2.5 will be packaged and sold non-sterile and must be sterilized prior to use. The device is not represented to be "pyrogen free." Medartis recommends sterilization in the specially designed sterilization containers, instrument trays and implant containers.

EQUIVALENCE TO MARKETED PRODUCT

The basis for Medartis AG's belief that the MODUS® TriLock® 2.0/2.3/2.5 System is substantially equivalent to the following predicate devices. Modus 2.5 Mandibular Resonstruction Set cleared under K992682, Modus Titanium Osteosynthesis System cleared under K050934, KLS Martin Mandibular/Reconstruction System II cleared under K032442, Synthes 2.0 mm Locking Plate System cleared under K974555, Synthes 2.4 Universal Locking Plate System cleared under K961421, Stryker Leibinger Locking Screw Mandibular Reconstruction Plate cleared under K000594 and OsteoMed 2.0 Locking Plate System cleared under K030448.

The plates of the subject system are the same as plates included in the predicate Modus Titanium Osteosynthesis System, except that the screw holes of the subject system plates are designed to accommodate TriLock HexaDrive® 6 locking screws.

MODUS® TriLock® 2.0/2.3/2.5 has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has similar packaging and is sterilized using the same materials and processes.

Medartis AG demonstrated that, for the purposes of FDA's regulation of medical devices, the MODUS® Trilock® 2.0/2.3/2.5 is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medartis AG
C/O Ms. Linda Schulz
Regulatory Affairs
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

SEP 11 2007

Re: K071612
Trade/Device Name: MODUS® Trilock® 2.0/2.3/2.5
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: September 4, 2007
Received: September 5, 2007

Dear Ms. Schulz:

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.

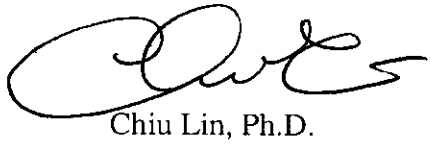
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K071612

1061

Indications for Use

510(k) Number (if known):

Device Name: MODUS® Trilock® 2.0/2.3/2.5

Indications for Use:

The MODUS® TriLock® 2.0/2.3/2.5 is intended for use in the mandible and mid-face region for osteotomies, severe fractures and comminuted fractures. These fractures may include condylar neck fractures, mandibular angle fractures, symphysis fractures, fractures of the atrophic mandible and fractures of the orbit and zygoma complex. Mandibular reconstruction may be performed with free or vascular bone graft.

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

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

510(k) Number: K071612

Page 1 of ___