AUG 2 2 2005

K051946

510(k): Summary

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, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	External Mandibular Fixator and/or Distractor
Trade/Proprietary Name:	Modus Modular Distraction Osteogenesis System
Common Name:	Mandibular Fixator and Distractor

ESTABLISHMENT REGISTRATION NUMBER

Medartis, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number has not yet been assigned. The owner/operator number for Medartis AG, the parent company of Medartis, Inc., is 9033581.

DEVICE CLASSIFICATION

FDA has classified bone fixation plates as Class II devices (21 CFR 872.4760). The product code for external mandibular fixator and/or distractor is MQN. This device classification is reviewed by the Dental Devices Branch.

INTENDED USE

The Modus Modular Distraction Osteogenesis System is a subcutaneous distractor system intended for use in fractures, osteotomies and arthrodeses including: treatment of hemifacial microsomia, mandibular hypoplasia, microglossia, defects of the alveolar

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ridge, atrophic bone segments in the mandible and maxilla, mandibular symphysis widening, growth disturbances of the ascending corpus/ascending ramus, LeFort I and LeFort II/III advancements.

DEVICE DESCRIPTION

Modus Plates

The Modus plates are used with the Modus Distraction Cylinders for various applications of the maxillofacial bone structures. The Modus plates are offered in a variety of sizes and are designed to fit the anatomy of the mandible and/or maxilla and allow adjustment of the vector by intra-operative bending if indicated.

Modus Distraction Cylinders

The Modus Distraction Cylinders are used with the Modus plates and screws for gradual bone distraction osteogenesis and for corrective osteotomies of the mandible and maxilla. The Modus distraction cylinders are available in uni-directional or bi-directional with multiple distraction lengths.

Modus Flexible Extensions

Flexible extensions are to be used with distraction cylinders if needed. The extensions allow additional access for distraction of the surgical site.

Material Composition

The implant plates and ARS distractors are made of CP titanium Grade 4 and comply with ASTM F 67 standards for unalloyed titanium for surgical implant applications. The MDO distraction cylinders and flexible extensions are made of implant steel that complies with ASTM F 138 or ASTM F 139.

EQUIVALENCE TO MARKETED PRODUCT

For the purposes of FDA's regulation of medical devices, the Modus Distraction System is substantially equivalent in indications and design principles to the predicate devices, that have been determined by FDA to be substantially equivalent to pre-amendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medartis, Incorporated
C/O Mr. Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K051946
Trade/Device Name: Modus Modular Distraction Osteogenesis System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: July 15, 2005
Received: July 19, 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,

for 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): K051946

Device Name: Modus Modular Distraction Osteogenesis System

Indications for Use:

The Modus® Modular Distraction Osteogenesis System is a subcutaneous distractor system intended for use in fractures, osteotomies and arthrodeses including: treatment of hemifacial microsomia, mandibular hypoplasia, microglossia, defects of the alveolar ridge, atrophic bone segments in the mandible and maxilla, mandibular symphysis widening, growth disturbances of the ascending corpus/ascending ramus, and LeFort I, and LeFort II/III advancements.

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)

Steven Runge

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

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