K052061

OCT 2 1 2005

510(k) Summary
Medartis, Inc.
MODUS® IMF Screws 2.0

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:	Implant, Endosseous, Root Form
Trade/Proprietary Name:	MODUS® IMF Screws 2.0
Common Name:	Intermaxillary fixation screw

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 root form endosseous implants as Class II Special Controls (21 CFR 872.3640). The product code is DZE. This device classification is reviewed by the Dental Devices Branch.

INTENDED USE

MODUS IMF Screws 2.0 are indicated for temporary use as a supplementary method in reduction and fixation of dislocated or fractured bone fragments, condylar fractures and restoration of occlusion in orthognathic or orthodontic procedures.

DEVICE DESCRIPTION

The MODUS IMF Screws 2.0 are provided in two screw types with different plateau geometries and various lengths. Both designs are self-drilling with cross heads and include holes for insertion of a wire parallel to the cross head as well as grooves for the attachment of elastic bands.

EQUIVALENCE TO MARKETED PRODUCT

For the purposes of FDA's regulation of medical devices, the MODUS IMF Screws 2.0 are substantially equivalent in indications and design principles to the predicate devices, each of which has 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

OCT 2 1 2005

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

Re: K052061
Trade/Device Name: MODUS IMF SCREWS 2.0
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: July 28, 2005
Received: August 3, 2005

Dear Mr. Larson:

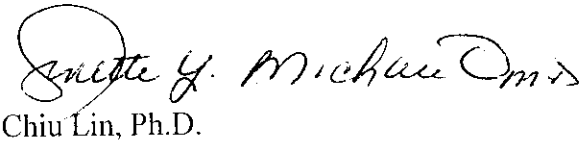
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): _____

Device Name: MODUS® IMF Screws 2.0

Indications for Use:

MODUS IMF Screws 2.0 are indicated for temporary use as a supplementary method in reduction and fixation of dislocated or fractured bone fragments, condylar fractures and restoration of occlusion in orthognathic or orthodontic procedures.

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)

Page 1 of 1

Susan Runner

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

510(k) Number: K052061