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510(k) Summary

JUN 28 2011

Medartis AG

APTUS® Foot 3.5 System

March 30, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Medartis AG Hochbergerstrasse 60E CH-4057 Basel, Switzerland Telephone: +41 61 633 34 34 Fax: +41 61 633 34 00
Official Contact:	Ulrike Jehle Regulatory Affairs Manager, Medartis AG
Representative/Consultant:	Kevin A. Thomas, PhD 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: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	APTUS® Foot 3.5 System
Common Name:	Plate, fixation, bone
Classification Regulations:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030, Class II
Product Codes:	HRS
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The APTUS® Foot 3.5 System is indicated for fractures and osteotomies of the calcaneus.

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DEVICE DESCRIPTION

The APTUS® Foot 3.5 System consists of titanium locking plates and titanium locking and non-locking screws. Plates are provided in three sizes in designs specifically for the right and left calcaneus. The plates are used with TriLock (locking) screws or cortical (non-locking) screws having self-tapping cortical thread forms and a thread diameter of 3.5 mm. The screws are provided in various overall lengths ranging from 16 mm to 60 mm. APTUS Foot 3.5 System plates are made of commercially pure titanium, Grade 4, conforming to ASTM F67. APTUS TriLock and cortical screws are made of titanium alloy conforming to ASTM F136.

EQUIVALENCE TO MARKETED DEVICE

APTUS® Foot 3.5 System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Synthes (USA), Synthes Locking Calcaneal Plates, cleared under K991407, and
Medartis AG, APTUS® Foot System, cleared under K091479.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar design characteristics. The subject and predicate devices encompass the same range of physical dimensions, are packaged using the similar materials, and are to be sterilized by the same methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance data was provided to demonstrate substantial equivalence and included detailed dimensional analysis of the subject and predicate designs, and testing of the subject and predicate plates and screws.

Overall, APTUS Foot 3.5 System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Medartis AG
% PaxMed International, LLC
% Kevin A. Thomas, Ph.D.
11234 El Camino Real, Suite 200
San Diego, CA 92130

JUN 28 2011

Re: K110908
Trade/Device Name: APTUS Foot 3.5 System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: June 7, 2011
Received: June 8, 2011

Dear Dr. Thomas:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

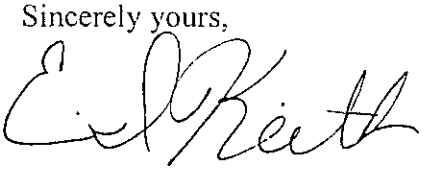
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K110908

Device Name: APTUS® Foot 3.5 System

Indications for Use:

The APTUS® Foot 3.5 System is indicated for fractures and osteotomies of the calcaneus.

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)

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for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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