

510(k) Summary

JUL 13 2009

**Medartis AG
APTUS® Foot System**

ADMINISTRATIVE INFORMATION

Manufacturer Name: Medartis AG
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 Regulatory Affairs Manager, Medartis AG

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 PaxMed International, LLC
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 flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: APTUS® Foot System
Common Name: Plate, fixation, bone
Classification Regulations: Single/multiple component metallic bone fixation appliances and accessories
 21 CFR 888.3030/21 CFR 888.3040
 Class II

Product Code: HRS/HWC
Classification Panel: Orthopedic Products Panel
Reviewing Branch: Orthopedic Devices Branch

INTENDED USE

The APTUS® Foot System is intended for use in small bones, in particular in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.

DEVICE DESCRIPTION

The APTUS® Foot System consists of small titanium fixation plates, conventional screws and locking screws. The system is intended to be used for internal fixation of small bones in the foot.

EQUIVALENCE TO MARKETED DEVICE

Medartis AG demonstrated that, for the purposes of FDA's regulation of medical devices, the APTUS® Foot System is substantially equivalent to previously cleared devices. The APTUS® Foot System 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 or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2009

Medartis AG
% Ms. Linda K. Schulz
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130

Re: K091479

Trade/Device Name: APTUS Foot 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: May 18, 2009

Received: May 19, 2009

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 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/cdrh/comp/> 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Handwritten signature of Mark N. Melkerson in black ink. The signature is cursive and includes the initials 'for' written below the main name.

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 (if known): K091479

Device Name: APTUS® Foot System

Indications for Use:

The APTUS® Foot System is intended for use in small bones, in particular in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.

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)

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for *[Signature]*
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091479