DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medartis AG
% Mr. Kevin A. Thomas
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

April 9, 2015

Re: K142581
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: Class II
Product Code: HRS, HWC
Dated: March, 4 2015
Received: March 6, 2015

Dear Mr. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142581

Device Name

APTUS® Foot System

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Medartis AG
APTUS® Foot System
K142581

April 7, 2015

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Foot System
Common Name	Plate, fixation, bone Screw, fixation, bone
Classification Names	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification Regulations	21 CFR 888.3030, 21 CFR 888.3040, Class II
Product Codes	HRS, HWC
Classification Panel Reviewing Branch	Orthopedic Products Panel Joint Fixation Devices Branch Two (JFDB2)

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 subject device plates are provided in a variety of anatomical designs, in various lengths, widths and thicknesses. The plate thickness varies from 1.6 mm to 2.0 mm depending on the design. The screw holes of the subject device plates are designed to accommodate appropriately sized subject device screws, or screws presently marketed as part of the APTUS System and previously cleared under K091479. The subject device plates also are compatible with K-wires cleared under K092038. The subject device plates are used with TriLock locking screws and cortical (nonlocking) screws. All subject device screws are self-tapping and self-drilling and provided in diameters of 2.0, 2.8 and 3.5 mm, and in various lengths from 8 to 45 mm.

The subject device plates are made of commercially pure titanium, Grade 4, conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*. The subject device screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*.

PERFORMANCE DATA

Performance data provided to demonstrate substantial equivalence included dimensional analysis, engineering analysis, finite element analysis, and mechanical testing. Subject device screws were tested as described in ASTM F543 *Standard Specification and Test method for Metallic Bone Screws*, including insertion torque, maximum torque, and pull-out testing (subject and predicate screws). Dynamic mechanical testing of the subject and predicate plate designs also was performed.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the following predicate devices:

K091479, APTUS® Foot System, Medartis AG;

K071264, Synthes (USA) 2.4/2.7 mm Locking Foot Module, Synthes (USA);

K100776, Synthes 2.4 mm / 2.7 mm Variable Angle LCP Forefoot / Midfoot System, Synthes (USA);

K090949, Synthes (USA) 1.5mm Headless Compression Screws, Synthes (USA); and

K101700, IO Fix Hand, IO Fix Foot, Extremity Medical Screw System, Extremity Medical LLC.

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, including plate screw holes to accommodate locking and non-locking screws. The subject MTP plates and the predicate K100776 MTP plates encompass the same range of precontoured dorsiflexion. The subject and predicate devices encompass the same range of physical dimensions, and the subject device is compatible with screws from the

predicate device K091479. The subject and predicate devices are packaged using the same materials, and are to be sterilized by the same methods. Any differences in the technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

CONCLUSION

The data included in this submission demonstrate substantial equivalence to the predicate devices listed.

Overall, the subject device 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.