510(k) Summary

Medartis AG

APTUS® Ulna Shortening 2.5

May 12, 2014

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:	Andrea Schweizer Group Manager Compliance & Vigilance
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 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® Ulna Shortening 2.5
Common Name:	Plate, fixation, bone Screw, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification Regulation:	21 CFR 888.3030, 21 CFR 888.3040, Class II
Product Code:	HRS, HWC
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Joint Fixation Devices Branch Two (JFDB2)

INTENDED USE

APTUS® Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.

DEVICE DESCRIPTION

APTUS Ulna Shortening 2.5 system consists of titanium locking plates. The plates are secured using previously cleared titanium screws (K103332 and K051567), both locking and non-locking. This submission includes additional lengths of non-locking screws. Plates have a low overall height, rounded edges, polished surfaces and incorporate TriLock Technology with use of TriLock (locking) screws. All plates are made from unalloyed titanium conforming to ASTM F67, and all screws are made from titanium alloy conforming to ASTM F136.

EQUIVALENCE TO MARKETED DEVICE

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

Medartis, Inc., APTUS® Titanium Fixation System, cleared under K051567;

Medartis AG, APTUS® Ulna Plates, cleared under K103332; and

TriMed Inc., TriMed Ulnar Osteotomy Plate, cleared under K043263.

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, and a screw hole angled for placement of a screw perpendicular to a 45° osteotomy. The subject and predicate devices encompass the same range of physical dimensions, and the subject device is compatible with screws from the predicate devices K103332 and K051567. 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 do not raise new issues of safety or efficacy.

Performance data provided to demonstrate substantial equivalence included detailed dimensional analysis of the subject and predicate device designs, engineering analysis and dynamic mechanical testing of the subject and predicate plate designs.

Overall, APTUS® Ulna Shortening 2.5 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 23, 2014

Medartis AG
% Mr. Kevin A. Thomas, PhD
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K141232
Trade/Device Name: APTUS® Ulna Shortening 2.5
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: May 12, 2014
Received: May 13, 2014

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 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,

Lori A. Wiggins

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

Enclosure

Indications for Use

510(k) Number: K141232

Device Name: APTUS® Ulna Shortening 2.5

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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)

Elizabeth D. Frank -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K141232