DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Medartis AG
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

September 8, 2017

Re: K172170
Trade/Device Name: APTUS® Wrist 2.5 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
Dated: July 17, 2017
Received: July 18, 2017

Dear Kevin 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 (DICE) 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" (21 CFR 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 (DICE) 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,

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)*

K172170

Device Name

APTUS® Wrist 2.5 System

Indications for Use *(Describe)*

APTUS® Wrist 2.5 System is intended for use in hand and forearm fractures, osteotomies, and arthrodeses.

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® Wrist 2.5 System

July 17, 2017

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Wrist 2.5 System
Common Name	Plate, fixation, bone
Classification Names	Single/multiple component metallic bone fixation appliances and accessories
Classification Regulations	21 CFR 888.3030
Product Codes	HRS
Classification Panel	Orthopedic Products Panel
Reviewing Branch	Joint Fixation Devices Branch Two (JFDB2)

PREDICATE DEVICE INFORMATION

The primary predicate device is K142906. The reference predicate device is K051567.

INDICATIONS FOR USE

APTUS® Wrist 2.5 System is intended for use in hand and forearm fractures, osteotomies, and arthrodeses.

SUBJECT DEVICE DESCRIPTION

The subject device plates have anatomic designs and are provided in two designs, each for the left and right radius: Lunate Facet Plate and Distal Radius Rim Plate. The Lunate Facet Plates have a maximum thickness of 1.6 mm, and maximum overall dimensions of approximately 19 mm x 47 mm before bending to conform to the anatomy of the distal radius. The Distal Radius Rim Plates have a maximum thickness of 1.8 mm, and maximum overall dimensions of approximately 22 mm x 53 mm before bending to

conform to the anatomy of the distal radius. The screw holes of the subject device plates are designed to accommodate appropriately sized bone screws (locking and non-locking) presently marketed as part of the APTUS System and previously cleared under K142906, K103332, and K051567. The subject device plates also are compatible with K-wires cleared under K092038. The subject device plates are made of unalloyed titanium, Grade 4, conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).*

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K142906), engineering analysis, static mechanical testing (according to ASTM F382), and dynamic mechanical testing of the subject and predicate plate designs in a simulated fracture model. Clinical data were not provided in this submission.

EQUIVALENCE TO MARKETED DEVICE

Medartis AG submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K142906, APTUS® Wrist 2.5 System, Medartis AG

K051567, APTUS® Titanium System, Medartis, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K142906 is provided in the following table.

Comparison	**Subject Device**	**Primary Predicate Device**
	APTUS Wrist 2.5 System Medartis AG	K142906 APTUS Wrist 2.5 System Medartis AG
Indications for Use Statement	APTUS® Wrist 2.5 System is intended for use in hand and forearm fractures, osteotomies, and arthrodeses.	APTUS® Wrist 2.5 System is intended for use in hand and forearm fractures, osteotomies and arthrodeses.
Device Characteristics		
Plate Designs	Anatomic plate designs (n=2) for left and right radius Lunate Facet Plate and Distal Radius Rim Plate	Anatomic plate designs (multiple) for left and right radius
Plate Thickness	Lunate Facet Plate – 1.6 mm Distal Radius Rim Plate – 1.8 mm	0.6 mm to 3.2 mm
Plate Overall Dimensions (approximate)	Lunate Facet Plate – 19 mm width x 47 mm length Distal Radius Rim Plate – 22 mm width x 53 mm length	Width: 7 mm to 36 mm Length: 7 mm to 184 mm
Plate Material	Unalloyed titanium, grade 4 (ASTM F67)	Unalloyed titanium, grade 4 (ASTM F67)
Information below for Subject Device is for previously cleared compatible screws		
Screw Designs	Self-drilling and self-tapping; Cortical (conventional non-locking) and locking	Self-drilling and self-tapping; Cortical (conventional non-locking) and locking
Screw Diameter	1.5 mm and 2.5 mm	1.5 mm and 2.5 mm
Screw Length	8 mm to 34 mm	8 mm to 34 mm
Screw Material	Ti-6Al-4V alloy (ASTM F136)	Ti-6Al-4V alloy (ASTM F136)

The subject device and the predicate device have the same intended use and the same Indications for Use statement.

The subject device and predicate device plates have the same technological characteristics are fabricated from the same materials and share similar design characteristics, including plate screw holes to accommodate locking and non-locking screws. The subject device and predicate device plates also are

provided in pre-contoured designs for the left and right radius, and encompass a similar range of physical dimensions appropriate to the anatomy. Any minor differences in the technological characteristics between the subject device and the predicate device do not raise new issues of safety or efficacy.

The subject device and predicate device plates are provided non-sterile and are to be sterilized by the end-user. The subject device components are packaged using the same materials and are to be sterilized by the same methods as the predicate device.

All of the subject device final finished components are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the predicate device components cleared in K142906, and therefore are substantially equivalent to the predicate device regarding biocompatibility.

Performance data provided to demonstrate substantial equivalence included engineering analysis, single cycle bending and bending fatigue testing of the subject device and predicate device plates. In addition, in a simulated fracture models, the dynamic (fatigue) performance of the subject device constructs was superior to that of the predicate device constructs.

Differences between the subject device and predicate device plates include differently shaped anatomic designs for the distal radius. The subject device and predicate device plates have a similar overall shape and similar maximum plate thickness (subject device plates 1.6 mm, predicate plates 1.6 mm and 2.0 mm). Substantial equivalence is supported by the mechanical testing of the subject device and predicate device plate and screw constructs.

CONCLUSION

The subject device and the predicate device plates have the same intended use, have similar technological characteristics, and are made of the same material. The subject device and predicate device plates also are provided in pre-contoured anatomic designs for the left and right radius, and encompass a similar range of physical dimensions appropriate to the anatomy. The subject device and predicate device components are packaged in similar materials and are to be sterilized by the end-user using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices K142906 and K051567.