November 8, 2019

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

Re: K192297
Trade/Device Name: APTUS Wrist Arthrodesis Plates
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: August 22, 2019
Received: August 23, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192297

Device Name

APTUS® Wrist Arthrodesis Plates

Indications for Use *(Describe)*

APTUS® Wrist Arthrodesis Plates are indicated for wrist arthrodesis.

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 Arthrodesis Plates

August 22, 2019

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 Kiefer-Schweizer Head of Quality Management and Regulatory Affairs
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA 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® Wrist Arthrodesis Plates
Common Name	Plate, fixation, bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Regulation	21 CFR 888.3030
Product Code	HRS
Classification Panel	Orthopedic
Reviewing Office	Office of Health Technology 6 (Orthopedic Devices)
Reviewing Division	Division of Health Technology 6 C (Restorative, Repair and Trauma Devices)

PREDICATE DEVICE INFORMATION

The primary predicate device is K112169, APTUS® Wrist Arthrodesis Plates, Medartis AG.

The reference devices are:

K142906, APTUS® Wrist 2.5 System, Medartis AG;
K042355, Synthes (USA) LCP Wrist Fusion Plates, Synthes (USA); and
K051567, APTUS® Titanium System, Medartis, Inc.

INDICATIONS FOR USE STATEMENT

APTUS® Wrist Arthrodesis Plates are indicated for wrist arthrodesis.

SUBJECT DEVICE DESCRIPTION

The subject device includes a total of seven (7) plates: five (5) plates are to be applied using a dorsal surgical approach, and have an anatomical design appropriate for either the left or right wrist; two (2) plates are to be applied using a volar surgical approach, and are provided in versions designed specifically for the left and right wrist. The dorsal plates have overall lengths ranging from approximately 61 mm to 116 mm, and maximum widths of 13.5 mm to 15.5 mm. The volar plates have overall lengths ranging from approximately 39 mm to 42 mm, and overall widths ranging from approximately 16 mm to 26 mm. The differences in the Indications for Use Statement for the subject device and the reference devices K142906 and K042355 include the additional language on the use of the reference devices (fractures and osteotomies) and specific examples of usage (K042355 and K051567). These minor differences do not impact substantial equivalence because all IFUS express equivalent intended use for internal fixation of the bones of the upper extremity.

The plates from the subject device, the primary predicate device, and the reference devices have the same technological characteristics, and have similar design characteristics, include designs for dorsal or volar surgical placement, and include screw holes to accommodate locking and nonlocking screws.

The plates from the subject device, the primary predicate device, and the reference devices encompass a similar range of physical dimensions (overall width, overall length, and thickness). The subject device and the primary predicate device K112169 both include plates with similar anatomic designs for dorsal surgical placement. Similarly, the subject device and the reference device K142906 both include plates with similar anatomic designs for volar surgical placement.

The plates from the subject device, K112169, K142906, and K051567 are manufactured from identical unalloyed titanium material conforming to ASTM F67. The plates from the subject device, K112169, and K142906 are compatible exclusively with previously cleared Medartis APTUS® screws, and also are compatible with previously cleared Medartis APTUS® K-Wires.

All subject device final, finished components are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the previously cleared Medartis device components (K112169, K142906, and K051567) and, therefore, are substantially equivalent to these devices regarding biocompatibility.

The subject device components and the Medartis device components cleared in K112169 and K142906 are packaged using the same materials, and are to be sterilized by the same methods. Any minor differences in the technological characteristics among the subject device and the devices in K112169 and K142906 do not impact safety or effectiveness.

The differences among the plates from the subject device, the primary predicate device, and the reference devices are variations in the designs of the plates (number of designs, overall dimensions, placement of screw holes), and variations in the sizes of the compatible screws. The plates and screws from the reference device K042355 are made of different materials compared to the subject device. These slight differences among the subject device and the predicate and reference devices do not impact safety or effectiveness.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility referenced from K112169, K142906, and K051567; engineering analysis; mechanical testing according to ASTM F382, and comparative dynamic mechanical testing in a simulated fracture model.

Mechanical performance of the subject device included testing according to ASTM F382 (dorsal plates), and worst-case construct fatigue testing (dorsal plates and volar plates). Based on the results of the testing, the performance of the subject device was judged to be substantially equivalent to the reference devices K142906 and K051567.

CONCLUSION

The subject device, the primary predicate device, and the reference device have the same intended use, have similar technological characteristics, and encompass a similar range of physical dimensions appropriate to the anatomy. The subject device and the primary predicate device are made of the identical material. The data included in this submission demonstrate substantial equivalence to the primary predicate device K112169 and reference devices K142906, K042355, and K051567.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	APTUS® Wrist Arthrodesis Plates Medartis AG	K112169 APTUS® Wrist Arthrodesis Plates Medartis AG	K142906 APTUS® Wrist 2.5 System Medartis AG	K042355 Synthes (USA) LCP Wrist Fusion Plates Synthes (USA)	K051567 APTUS® Titanium System Medartis, Inc.
Indications for Use Statement	APTUS® Wrist Arthrodesis Plates are intended for wrist arthrodesis.	APTUS® Wrist Arthrodesis Plates are intended for wrist arthrodesis.	APTUS® Wrist 2.5 System is intended for use in hand and forearm fractures, osteotomies and arthrodeses.	Synthes (USA) LCP Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.	The APTUS® Titanium Fixation System is intended for use in hand and forearm fractures, osteotomies and arthrodeses. APTUS® Hand group: • Management of the fractures of the distal, middle and proximal phalanges and metacarpals • Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft factures, comminuted fractures, dislocation fractures, avulsion fractures • DIP and PIP arthrodeses APTUS® Radius 2.5 group: • Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures • Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions.
Product Code	HRS	HRS	HRS, HWC	HRS	HRS
Intended Use	Internal fixation of the upper extremity	Internal fixation of the upper extremity	Internal fixation of the upper extremity	Internal fixation of the upper extremity	Internal fixation of the upper extremity
Reason for Predicate/Reference Device	Not applicable	Identical IFUS; Similar plate designs for dorsal surgical placement; Same compatible screws	Similar IFUS; Similar plate designs for volar surgical placement; Same compatible screws	Similar IFUS; Similar plate designs for dorsal surgical placement; Comparison in mechanical testing	Similar IFUS; Similar plate designs for volar surgical placement; Same compatible screws; Comparison in mechanical testing
Plates					
Plate Design	Anatomic plate designs Multiple sizes Multiple designs Designs for dorsal and volar surgical placement Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs Multiple sizes Multiple designs Designs for dorsal surgical placement Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs Multiple sizes Multiple designs Designs for dorsal and volar surgical placement Screw holes accommodate locking and non-locking (cortex) screws	Pre-contoured, limited contact, locking compression plates Designs for dorsal surgical placement Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs (multiple) Multiple sizes Multiple designs Designs for volar and dorsal surgical placement Screw holes accommodate locking and non-locking (cortex) and locking screws
Plate Overall Dimensions (Approximate)	Dorsal plates Widths 13.5-15.5 mm, Lengths 61-116 mm Volar plates Widths 16-26 mm, Lengths 39-42 mm	Dorsal plates Widths 17-23 mm, Lengths 59-115 mm	All plates Widths 7-36 mm, Lengths 7-184 mm	11 mm width *(Lengths not stated in 510(k) summary)*	All plates Widths 3.2-34 mm, Lengths 18-63 mm
Plate Thickness	1.6 mm to 2.6 mm	1.8 mm to 2.6 mm	0.6 mm to 3.2 mm	3.3 mm	0.6 mm to 1.6 mm
Plate Material	Unalloyed titanium, ASTM F67, grade 4	Unalloyed titanium, ASTM F67, grade 4	Unalloyed titanium, ASTM F67, grade 4	Titanium alloy; stainless steel alloy	Unalloyed titanium, ASTM F67, grade 4

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	APTUS® Wrist Arthrodesis Plates Medartis AG	K112169 APTUS® Wrist Arthrodesis Plates Medartis AG	K142906 APTUS® Wrist 2.5 System Medartis AG	K042355 Synthes (USA) LCP Wrist Fusion Plates Synthes (USA)	K051567 APTUS® Titanium System Medartis, Inc.
Screws					
Screw Design	*Previously cleared Medartis APTUS Screws (K051567, K103332):* *Locking screws:* *Cortical thread form, double-lead thread, self-tapping, fully threaded* *Non-locking screws:* *Cortical thread form, single-lead thread, self-tapping, fully threaded*	*Previously cleared Medartis APTUS Screws (K051567, K103332):* *Locking screws:* *Cortical thread form, double-lead thread, self-tapping, fully threaded* *Non-locking screws:* *Cortical thread form, single-lead thread, self-tapping, fully threaded*	Locking screws: Cortical thread form, double-lead thread, self-drilling, self-tapping, fully threaded Non-locking screws: Cortical thread form, single-lead thread, self-drilling, self-tapping, fully threaded *Previously cleared Medartis APTUS Screws (K051567, K103332):* *Locking screws:* *Cortical thread form, double-lead thread, self-tapping, fully threaded* *Non-locking screws:* *Cortical thread form, single-lead thread, self-tapping, fully threaded*	Locking screws and cortex (non-locking) screws	Locking screws: Cortical thread form, double-lead thread, self-tapping, fully threaded Non-locking screws: Cortical thread form, single-lead thread, self-tapping, fully threaded
Screw Diameter	*Previously cleared:* *2.5 mm (locking and non-locking)*	*Previously cleared:* *2.5 mm (locking and non-locking)*	*Previously cleared:* *1.5 mm and 2.5 mm*	2.7 mm and 3.5 mm (locking and non-locking)	1.2 mm to 2.5 mm
Screw Length	*Previously cleared:* *8 mm to 24 mm (non-locking)* *8 mm to 34 mm (locking)*	*Previously cleared:* *8 mm to 34 mm (locking and non-locking)*	*Previously cleared:* *Various lengths*	2.7 mm Ø: 10 mm to 24 mm 3.5 mm Ø: 12 mm to 28 mm *(From product labeling, not stated in 510(k) Summary)*	4 mm to 34 mm
Screw Material	*Previously cleared:* *Ti-6Al-4V alloy, ASTM F136*	*Previously cleared:* *Ti-6Al-4V alloy, ASTM F136*	*Previously cleared:* *Ti-6Al-4V alloy, ASTM F136*	Titanium alloy, stainless steel alloy *(From product labeling, not stated in 510(k) Summary)*	Ti-6Al-4V alloy, ASTM F136
K-Wires					
Design	*Previously cleared Medartis APTUS K-Wires (K092038):* *Ø 1.6 mm*	*Previously cleared Medartis APTUS K-Wires (K092038):* *Ø 1.6 mm*	*Previously cleared Medartis APTUS K-Wires (K092038):* *Ø 1.6 mm*		
Material	*Previously cleared:* *Stainless steel alloy, ASTM F138*	*Previously cleared:* *Stainless steel alloy, ASTM F138*	*Previously cleared:* *Stainless steel alloy, ASTM F138*		
How Provided					
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	Not stated in 510(k) Summary	Provided non-sterile
Sterilization	End user to sterilize by moist heat	End user to sterilize by moist heat	End user to sterilize by moist heat	Not stated in 510(k) Summary	End user to sterilize by moist heat
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use