February 16, 2020

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: K193554
Trade/Device Name: APTUS® Forearm Shaft Plates and 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: December 19, 2019
Received: December 20, 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, M.P.H.
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)*

K193554

Device Name

APTUS® Forearm Shaft Plates and APTUS® Wrist 2.5 System

Indications for Use *(Describe)*

APTUS® Forearm Shaft Plates are intended for management of fractures and osteotomies of the radius and ulna shaft.

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

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K193554

Medartis AG

APTUS® Forearm Shaft Plates and APTUS® Wrist 2.5 System

February 10, 2020

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Forearm Shaft Plates and APTUS® Wrist 2.5 System
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

Primary Predicate Device
K142906, APTUS® Wrist 2.5 System, Medartis AG.

Reference Devices
K000684, Small Fragment Dynamic Compression Locking (DCL) System, Synthes (USA),
K103332, APTUS® Ulna Plates, Medartis AG, and
K151468, ARIX Wrist System, Jeil Medical Corporation.

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INDICATIONS FOR USE STATEMENT

APTUS® Forearm Shaft Plates are intended for management of fractures and osteotomies of the radius and ulna shaft.
APTUS® Wrist 2.5 System is intended for use in hand and forearm fractures, osteotomies and arthrodeses.

SUBJECT DEVICE DESCRIPTION

The subject device includes a total of 10 bone plates for internal fixation of the shaft of the radius and ulna, and hook plates for fixation of avulsed fragments of the distal radius or ulna. All plates have anatomical designs that are appropriate for either the left or right forearm.

The plates for the shaft of the radius and ulna have similar designs, are provided in designs with 10, 14, 18, or 22 holes, with overall lengths ranging from 80 mm to 160 mm. All plates for the shaft of the radius and ulna have a maximum width of 10 mm, a maximum thickness of 3.4 mm, and the width and thickness taper at the ends of the plates. The radius shaft plates have a slight curvature to match the anatomy of the radius; the ulna shaft plates are straight.

The subject device hook plates are provided in two designs: a design with two curved hooks and six (6) holes, and a design with four (4) curved hooks and twelve (12) holes. The hook plates have approximate overall dimensions of 8.5 mm width by 17.5 mm length, or 18.5 mm width by 17.5 mm length; both plates are 0.6 mm thick.

The subject device plates include screw holes designed to accommodate appropriately sized bone screws and K-wires presently marketed as part of the APTUS® System. The compatible screws are 2.8 mm in diameter (shaft plates) and 1.5 mm in diameter (hook plates) and were previously cleared in K091479, K103332, and K142906. The subject device plates also are compatible with 1.6 mm diameter Medartis APTUS® K-Wires previously cleared in K092038.

All subject device plates are manufactured from unalloyed titanium conforming to ASTM F67.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility and sterilization referenced from K142906 and K103332; engineering analysis; and mechanical testing according to ASTM F382. Clinical data were not provided in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above.

The subject device, the primary predicate device, and reference devices have the same intended use for internal fixation of the bones of the upper extremity. The IFUS for the subject device includes a statement for the shaft plates and a statement for the hook plates. The statement for the hook plates is identical to the IFUS for the primary predicate device K142906.

The differences in the IFUS for the subject device shaft plates compared to that of the primary predicate device and the reference devices include: the specific language in the subject device IFUS referring to the radius and ulna shaft that is not in the other IFUS statements; language referring to fixation of additional bones in the IFUS for K000684; and the language referring to osteopenic bone in the IFUS for K000684.

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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 K142906, and the reference devices K000684 and K103332 have the same technological characteristics, have similar design characteristics, and include screw holes to accommodate locking and non-locking screws.

The plates from the subject device, the primary predicate device K142906, and the reference devices K000684 and K103332 encompass a similar range of physical dimensions (overall width, overall length, and thickness). The subject device and K000684 include plates for the radius and ulna shaft with similar designs and dimensions. Similarly, the subject device and K142906 both include plates with similar designs for hook plates. The plates from the subject device, K142906, and K103332 are manufactured from identical unalloyed titanium material. The plates from the subject device, K142906, and K103332 also are compatible exclusively with previously cleared Medartis APTUS® screws, and also are compatible with previously cleared Medartis APTUS® K-Wires.

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 previously cleared Medartis device components (K142906 and K103332) and, therefore, are substantially equivalent to these devices regarding biocompatibility.

The subject device components and the Medartis device components cleared in K142906 and K103332 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 K142906 and K103332 do not impact safety or effectiveness.

The differences among the plates from the subject device, K142906, K000684, and K103332 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 K000684 are made of different material (titanium alloy) compared to the subject device. These slight differences among the subject device and the predicate and reference devices do not impact safety or effectiveness.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and encompass a similar range of physical dimensions appropriate to the anatomy. The data included in this submission demonstrate substantial equivalence to the primary predicate device and the reference devices listed above.