September 30, 2019

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

Re: K191848
Trade/Device Name: APTUS Wrist Spanning Plates 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: August 1, 2019
Received: August 2, 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)*
K191848

Device Name

APTUS® Wrist 2.5 System

Indications for Use *(Describe)*

APTUS® Wrist Spanning Plates 2.5 are intended for use in forearm fractures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Medartis AG

APTUS® Wrist 2.5 System

July 9, 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 Schweizer Head of Quality Management
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DEVICE NAME AND CLASSIFICATION

Trade/Device Name	APTUS® Wrist 2.5 System
Common Name	Plate, Fixation, Bone
Regulation Number	21 CFR 888.3030
Regulation Name	Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	Class II
Product Code	HRS
Classification Panel	Orthopedic Products Panel
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 Device
K131764, Acumed Wrist Spanning Plate, Acumed, LLC

INDICATIONS FOR USE STATEMENT

APTUS® Wrist Spanning Plates 2.5 are intended for use in forearm fractures.

SUBJECT DEVICE DESCRIPTION

The subject device includes plates to be applied using a dorsal surgical approach: two (2) plates with an anatomical pre-bent design specifically for the left and right wrist; and an additional plate design appropriate for either the left or right wrist. The plates have an overall length of 196 mm, a maximum width of 10 mm, and a maximum thickness of 3.4 mm tapering to 1.6 mm. The plates are made from titanium alloy conforming to ASTM F136. The plates are designed to accommodate appropriately sized bone screws presently marketed as part of the APTUS® System and previously cleared in K103332 (cortical screws) and K051567 (TriLock locking screws). The subject device plates also are compatible with Medartis APTUS® K-Wires previously cleared in K092038.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation according to ISO 11137-1, ISO 11137-2, and ISO 11137-3; bacterial endotoxin testing according to ANSI AAMI ST72; sterile barrier shelf life testing according to ISO 11607-1, ISO 11607-2, ASTM F1980, ASTM D4332, ASTM D4169, ASTM F2096, DIN EN 868-5, and ASTM F88/F88M; biocompatibility testing according to ISO 10993-5, ISO 10993-12, ISO 10993-15, and ISO 10993-18; and comparative mechanical testing according to ASTM F382. Clinical data were not provided in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference device listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference device.

The primary predicate device K142906 is for support of substantial equivalence based upon a similar Indications for Use Statement (IFUS), similar device designs, and identical materials. The reference device K131764 is for support of substantial equivalence based upon a similar IFUS, similar device designs, similar materials, and performance in side-by-side mechanical testing.

The subject device, the primary predicate device, and reference device have the same intended use for internal fixation of the wrist. The IFUS is similar for the subject device, the primary predicate device K142906, and the reference device K131764. The IFUS for K142906 includes language for use in the hand and for osteotomies and arthrodeses. The IFUS for K131764 includes language concerning osteotomies, non-unions, and the radius. These slight differences in language do not impact substantial equivalence because the subject device and the devices cleared in K142906 and K131764 are intended for similar fixation (fusions) of the upper extremity.

The subject device and the primary predicate device K142906 have the same technological characteristics and are fabricated from identical titanium alloy conforming to ASTM F136. The subject device and the primary predicate device K142906 also are compatible with the same previously-cleared screws and K-Wires. The reference device K131764 also is fabricated from titanium alloy conforming to ASTM F136, and has similar design features. The subject device, the primary predicate device K142906, and the reference device K131764 all include plates that are to be placed by a dorsal surgical approach, and are to be fixed with locking and non-locking bone screws.

The titanium alloy material of the subject device in its final finished form is identical to the titanium alloy used in the primary predicate K142906 in formulation and processing. The subject device is manufactured

in the same facilities using the same manufacturing processes as used for the components previously cleared in K142906.

The subject device and the reference device K131764 are provided sterile to the end user; the sterilization method is not stated in the 510(k) Summary for K131764.

The subject device plates are slightly longer than the reference device K131764; this difference does not impact safety or effectiveness because the plates are to be used in an anatomic location that can safely accommodate a slightly longer plate design.

The subject device plates are to be used with a smaller number of fixation screws, and smaller size (diameter) screws than the reference device K131764. These differences are mitigated by the mechanical testing according to ASTM F382 that demonstrated the subject device plates to be substantially equivalent to the reference device plates cleared in K131764.

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 K142906 and the reference device K131764.