August 24, 2018

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

Re: K181009
Trade/Device Name: APTUS CMC-I Fusion Plate 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 23, 2018
Received: July 24, 2018

Dear Kevin A. Thomas, Ph.D.:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K181009

Device Name

APTUS® CMC-I Fusion Plate System

Indications for Use *(Describe)*

The APTUS® CMC-I Fusion Plate System is intended to be used for fusion of the trapezium with the first metacarpal.

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.

510(k) Summary

Medartis AG

APTUS® CMC-I Fusion Plate System

April 17, 2018

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
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® CMC-I Fusion Plate 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 Products Panel
Reviewing Branch	Joint Fixation Devices Branch Two (JFDB2)

PREDICATE DEVICE INFORMATION

The primary predicate device is K062498, Profyle® System, Howmedica Osteonics Corporation.
The reference predicate device is K051567, APTUS® Titanium System, Medartis, Inc.

INDICATIONS FOR USE

The APTUS® CMC-I Fusion Plate System is intended to be used for fusion of the trapezium with the first metacarpal.

SUBJECT DEVICE DESCRIPTION

The subject device plate has an anatomical design appropriate for both the left and right wrist. The plate has a uniform thickness of 1.3 mm and has overall dimensions of approximately 35 mm x 13 mm, before bending to conform to the hand anatomy. The screw holes of the plate are designed to accommodate appropriately sized bone screws presently marketed as part of the APTUS® System and previously cleared under K051567. The subject device plate is compatible with 2.0 mm diameter screws, and is used with TriLock locking screws and cortical (nonlocking) screws. The subject device plate is made of unalloyed titanium conforming to ASTM F67.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K051567), mechanical testing (according to ASTM F382), and comparative dynamic testing 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:

K062498, Profyle® System, Howmedica Osteonics Corporation; and

K051567, APTUS® Titanium System, Medartis, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K062498 is provided in the following table.

	Subject Device	**Primary Predicate Device**
Comparison	APTUS® CMC-I Fusion Plate System Medartis AG	K062498 Profyle® System Howmedica Osteonics Corporation
Indications for Use Statement	The APTUS® CMC-I Fusion Plate System is intended to be used for fusion of the trapezium with the first metacarpal.	The Profyle® System is intended for use in internal fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.
Device Characteristics		
Plate Designs	Anatomic plate design One size Single design for right and left hand-wrist; Screw holes accommodate conventional (cortex) and locking screws	Anatomic plate designs Multiple sizes Multiple designs Screw holes accommodate conventional (cortex) and locking screws
Plate Overall Dimensions (Approximate)	13 mm width x 35 mm length	Various
Plate Thickness	Uniform thickness, 1.3 mm	Uniform thickness, range from 0.55 mm – 1.5 mm
Plate Material	Unalloyed titanium, grade 4 (ASTM F67)	Unalloyed titanium, grade 2
Screw Designs	***Previously cleared:*** *Locking screws: cortical thread form, double thread, self-tapping, fully threaded* *Non-locking screws: cortical thread form, single thread, self-tapping, fully threaded* *Cannulated screws: cortical thread form, single thread, self-tapping, partially threaded, cannulated*	Cortical thread form Self-tapping, fully threaded Conventional (non-locking) and locking
Screw Diameter	***Previously cleared:*** *2.0 mm (locking and non-locking)* *3.0 mm (cannulated)*	1.2 mm to 2.5 mm

	Subject Device	Primary Predicate Device
Screw Length	***Previously cleared:*** *8 mm to 20 mm (conventional and locking)* *18 mm to 32 mm (cannulated)*	6 mm to 26 mm
Screw Material	***Previously cleared:*** *Ti-6Al-4V alloy, ASTM F136*	Ti-6Al-4V alloy

The subject device, the primary predicate device K062498, and reference predicate device K051567 have the same intended use for internal fixation of the bones of the hand and wrist, and have the same technological characteristics. The subject device and the plates from both predicate devices (K062498 and K051567) are fabricated from unalloyed titanium. The subject device and the reference predicate device K051567 have similar design characteristics, including the design of screw holes to accommodate locking and non-locking screws. The subject device and both predicate devices (plates) encompass a similar range of physical dimensions (overall width, length, and thickness). The subject device plates are compatible exclusively with screws from the reference predicate device K051567.

The differences between the subject device and primary predicate device K062498 are slight variations in the design of the plates and compatible screws. The differences between the subject device and reference predicate device K051567 plates are the specific design configurations and dimensions. These slight differences among the subject device and predicate devices do not raise new issues of safety or efficacy.

The final finished subject device is manufactured in the same facilities using identical materials and identical manufacturing processes as used for the previously cleared reference predicate device components cleared in K051567, and therefore are substantially equivalent to the reference predicate device regarding biocompatibility. The subject device and reference predicate device K051567 components are packaged using the same materials, and are to be sterilized by the same methods.

The Indications for Use Statement for the subject device is similar to that of the primary predicate device K062498. The slight differences in wording do not affect the intended use for internal fixation of the hand and wrist.

Performance data provided to demonstrate substantial equivalence included four-point bend testing (according to ASTM F382), and comparative dynamic testing in a simulated fracture model.

CONCLUSION

The subject device plates and the primary predicate device plates have the same intended use, have similar technological characteristics, encompass a similar range of physical dimensions appropriate to the anatomy and are made of the same material. The subject device and reference predicate device K051567 are packaged in similar materials and are to be sterilized by the end-user using similar methods. Performance data demonstrated the subject device plates to be substantially equivalent to K062498.

The data included in this submission demonstrate substantial equivalence to the predicate devices K062498 and K051567.