DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 9, 2017

Medartis AG
Kevin Thomas
Paxmed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K161861
Trade/Device Name: APTUS® Coronoid 2.0
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: January 11, 2017
Received: January 12, 2017

Dear Mr. 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 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 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)*

K161861

Device Name

APTUS® Coronoid 2.0

Indications for Use *(Describe)*

ATPUS Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.

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® Coronoid 2.0

January 11, 2017

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Coronoid 2.0
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 Reviewing Branch	Orthopedic Products Panel Joint Fixation Devices Branch Two (JFDB2)

PREDICATE DEVICE INFORMATION

Primary predicate device: K071715, Acumed Congruent Bone Plate System, Acumed LLC

Reference predicate device: K142906, APTUS® Wrist 2.5 System, Medartis AG

INDICATIONS FOR USE

ATPUS Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.

DEVICE DESCRIPTION

The subject device APTUS Coronoid 2.0 plates have an anatomical design and are provided for the left and right ulna. The plates have a uniform thickness of 1.6 mm. The subject device plates are compatible with 2.0 mm diameter screws, and are used with TriLock locking screws and cortical (nonlocking) screws. The compatible screws have cortical threads, are presently marketed as part of the APTUS System, and were cleared under K051567 and K090053. The subject device plates also are compatible with K-wires cleared under K092038. The subject device plates are made of commercially pure 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), dimensional analysis, single cycle bending and bending fatigue testing of the subject device plates and the primary predicate device plates (according to ASTM F382), and dynamic compression testing of the subject device plates and the primary predicate device plates in a simulated coronoid fracture model. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Medartis AG submits the following 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:

K071715, Acumed Congruent Bone Plate System, Acumed LLC; and

K142906, APTUS® Wrist 2.5 System, Medartis AG.

A comparison of the technological characteristics of the subject device and the primary predicate device K071715 is provided in the following table.

Comparison	Subject Device Medartis AG APTUS® Coronoid 2.0	Primary Predicate Device Acumed Congruent Bone Plate System K071715
Indications for Use	ATPUS Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.	The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia and fibula.
Plates		*Information below for predicate coronoid plates*
Design	Anatomical plate designs for left and right ulna	Anatomical plate designs for left and right ulna
Thickness	1.6 mm	1.6 mm
Overall Dimensions (approximate)	28 mm x 34 mm (before bending)	(20-21 mm) x (31-35 mm)
Material	Unalloyed titanium ASTM F67, anodized blue	Unalloyed titanium ASTM F67; anodized blue, green
Screws	*Information below for previously cleared compatible screws*	
Design	Self-tapping cortical (nonlocking) screws Self-tapping TriLock locking screws	Self-tapping cortical screws Self-tapping locking screws
Diameter	2.0 mm	2.7 mm
Length	Cortical screws 4 to 24 mm TriLock screws 6 to 30 mm	8 to 32 mm
Material	Ti-6Al-4V alloy, ASTM F136	Ti-6Al-4V alloy, ASTM F136

The subject device coronoid plates and the primary predicate device coronoid plates have the same intended use and have the same technological characteristics. The subject and primary predicate device plates are fabricated from the same materials and share similar design characteristics, including plate screw holes to accommodate locking and non-locking screws. The subject and primary predicate device plates also are provided in pre-contoured designs for the left and right ulna, and encompass a similar range of physical dimensions appropriate to the coronoid anatomy. Any minor differences in the technological characteristics between the subject device and the primary predicate device do not raise new issues of safety or efficacy.

The subject and primary predicate device plates are provided nonsterile and are to be sterilized by the end-user. The subject devices are packaged using the same materials and are to be sterilized by the same methods as the reference 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 previously cleared reference predicate devices in K142906, and therefore are substantially equivalent to the reference predicate with regard to biocompatibility.

The wording of the Indications for Use for the subject device is slightly different than that of the primary predicate device; however, the slight differences in wording do not change the intended use of the subject device as compared to the primary predicate device.

Performance data provided to demonstrate substantial equivalence included single cycle bending and bending fatigue testing of the subject device and predicate device plate and screw constructs. In both single cycle bending and bending fatigue testing, the performance of the subject device constructs was superior to that of the predicate device constructs. In addition, in a simulated coronoid fracture model, the performance of the subject device constructs also was superior to that of the predicate device constructs.

Differences between the subject device and the primary predicate K071715 include differently shaped anatomic designs for the coronoid, and the use of 2.0 mm diameter screws (subject device) versus 2.7 mm diameter screws (primary predicate device). Substantial equivalence is supported by the single cycle and dynamic mechanical testing of the subject device and predicate device plate and screw constructs.

CONCLUSION

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

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.