August 5, 2018

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: K181425
Trade/Device Name: APTUS® Proximal Humerus 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, HWC, HTY
Dated: May 29, 2018
Received: May 31, 2018

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. 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.

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,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2018.08.05 23:38:47 -04'00'

For: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181425

Device Name

APTUS® Proximal Humerus System

Indications for Use *(Describe)*

APTUS® Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus.

The APTUS® K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

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® Proximal Humerus System

July 20, 2018

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Proximal Humerus System
Common Name	Plate, fixation, bone Pin, fixation, smooth Screw, fixation, bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Regulations	21 CFR 888.3030 21 CFR 888.3040
Product Codes	HRS, HTY, HWC
Classification Panel	Orthopedic Products Panel

PREDICATE DEVICE INFORMATION

The primary predicate device is K120108. Additional predicate devices are K041860, K092038, and K960385.

INDICATIONS FOR USE STATEMENT

APTUS® Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus.

The APTUS® K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

SUBJECT DEVICE DESCRIPTION

The subject device includes four (4) plate designs to expand the range of Medartis APTUS® Proximal Humerus Fixation devices previously cleared in K120108, and two (2) additional K-wire designs, to expand the range of Medartis APTUS® K-Wires previously cleared in K092038. The subject plates are provided in 10-hole and 14-hole designs, each in anatomic designs for the right and left proximal humerus. The subject plates range in length from approximately 180 mm (10-hole plate) to approximately 230 mm (14-hole plate). The proximal region of the subject plates is identical to the devices previously cleared in K120108. This submission includes a spiral locking blade for use with the subject plates that is similar to the spiral blades cleared in K120108. The subject plates are to be used with previously cleared 3.5 mm diameter locking screws and non-locking (cortical) screws. The subject device plates and spiral blades are made of unalloyed titanium conforming to ASTM F67.

The subject device K-wires have a diameter of 2.0 mm and an overall length of 150 mm, and are provided with a trocar tip or lancet (bayonet) tip. The subject device K-wires are also compatible with the subject plates, and with the proximal humerus plates cleared in K120108. The subject K-wires are made of stainless steel conforming to ASTM F138.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K120108 and K092038), mechanical testing (according to ASTM F382), engineering analysis calculations of out-of-plane bending moments of inertia, 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:

K120108, APTUS® Proximal Humerus System, Medartis AG;

K041860, Synthes (USA) LCP® Proximal Humerus Plates, Long, Synthes (USA);

K092038, APTUS® K-Wire System, Medartis AG; and

K960385, Sterile Kirschner Wires and Steinmann Pins, DePuy, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K120108 is provided in the following table.

	Subject Device	**Primary Predicate Device**
Comparison	APTUS® Proximal Humerus System Medartis AG	K120108 APTUS® Proximal Humerus System Medartis AG
Indications for Use Statement	APTUS® Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus. The APTUS® K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.	APTUS® Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus.
Device Characteristics		
Plate Designs	Anatomic plate design Multiple sizes: 10 and 14 shaft screw hole plates; Specific plates for right and left proximal humerus;	Anatomic plate design Multiple sizes: 3, 5, and 7 shaft screw hole plates; Specific plates for right and left proximal humerus;

	Subject Device	Primary Predicate Device
Comparison	APTUS® Proximal Humerus System Medartis AG	K120108 APTUS® Proximal Humerus System Medartis AG
	Screw holes accommodate conventional and locking screws; Locking blades	Screw holes accommodate conventional and locking screws; Locking blades
Plate Thickness	Proximal: 3.0 mm Shaft: 3.8 mm	Proximal: 3.0 mm Shaft: 3.0 mm
Plate Material	Unalloyed titanium, grade 4 (ASTM F67)	Unalloyed titanium, grade 4 (ASTM F67)
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*	Locking screws: cortical thread form, double thread, self-tapping, fully threaded Non-locking screws: cortical thread form, single thread, self-tapping, fully threaded
Screw Diameter	***Previously cleared:*** *3.5 mm (locking and non-locking)*	3.5 mm
Screw Length	***Previously cleared:*** *Locking and non-locking:* *16 mm to 60 mm*	Locking and non-locking: 16 mm to 60 mm
Screw Material	***Previously cleared:*** *Ti-6Al-4V alloy (ASTM F136)*	Ti-6Al-4V alloy (ASTM F136)

The Indications for Use Statement for the subject device (plates) is identical to that that of the primary predicate device K120108. The Indications for Use Statement for the subject device (K-Wires) is identical to that of the additional predicate device K092038.

The plates from the subject device, the primary predicate device K120108, and additional predicate device K041860 have the same intended use for fixation of the proximal humerus, and have the same technological characteristics. The plates from the subject device and the primary predicate device K120108 are fabricated from the identical unalloyed titanium material. The plates from the subject device and the primary predicate device K120108 have the same or similar design characteristics, including the design of the proximal region of the plate, screw holes to accommodate locking and non-locking screws, and the design of the spiral blade components. The plates from the subject device, primary predicate device K120108, and additional predicate device K041860 encompass a similar same range of physical dimensions (overall lengths and thicknesses). The subject device plates are compatible with screws from the primary predicate device K120108, as well as K110908. The difference between the subject device and primary predicate device K121018 is the longer lengths of the subject device plates. The additional predicate K041860 is for substantial equivalence of the longer plate lengths (extending to the humeral shaft).

The K-wires from the subject device and the additional predicate devices K092038 and K960385 have the same intended use and have the same technological characteristics. The K-wires from the subject device and the additional predicate device K092038 are fabricated from the identical stainless steel material. The K-wires from the subject device and the additional predicate device K092038 have the same characteristics, except for the diameter of the wires. The additional predicate device K960385 is for substantial equivalence of the larger diameter (2 mm) of the subject device K-wires.

Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that the unalloyed titanium and stainless steel materials used in the subject devices are identical in formulation, processing, component interactions, and storage conditions to the predicate devices in K120108 and K092038.

Performance data provided to demonstrate substantial equivalence included mechanical testing (according to ASTM F382), and engineering analysis calculations of out-of-plane bending moments of inertia, and comparative dynamic testing in a simulated fracture model. The data demonstrated substantial equivalence to the primary predicate device K120108 and the additional predicate device K041860.

CONCLUSION

The subject device plates and the primary predicate device (K120108) plates have the same intended use, have similar technological characteristics, and are made of the same material. The subject device plates and primary predicate device (K120108) plates also are provided in pre-contoured anatomic designs for the left and right radius, and encompass a similar range of physical dimensions appropriate to the anatomy. The subject device and primary predicate device K120108 components are packaged in similar materials and are to be sterilized by the end-user using similar methods. The subject device plates and the additional predicate device K041860 include designs in lengths for treatment of the humeral shaft. Performance data demonstrated the subject device plates to be substantially equivalent to the primary predicate device K120108 and to the additional predicate device K041860.

The subject device K-wires have the same intended use, have similar technological characteristics, and are made of the same material as the additional predicate K092038. The subject device and primary predicate device components are packaged in similar materials and are to be sterilized by the end-user using similar methods. The subject device K-wires are substantially equivalent in diameter to the additional predicate device K960385.

The data included in this submission demonstrate substantial equivalence to the predicate devices K120108, K041860, K092038, and K960385.