March 26, 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: K193639
Trade/Device Name: APTUS® Foot 2.8-3.5 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, HWC, PLF
Dated: December 27, 2019
Received: December 27, 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)*

K193639

Device Name

APTUS® Foot 2.8-3.5 System

Indications for Use *(Describe)*

The APTUS® Foot 2.8-3.5 System is intended for use in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.

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

K193639

Medartis AG

APTUS® Foot 2.8-3.5 System

March 20, 2020

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Foot 2.8-3.5 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, PLF, HWC
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
K091479, APTUS® Foot System, Medartis AG

Additional Predicates
K061808, DARCO Locking Bone Plate System, DARCO International, Inc.
K052614, Arthrex Low Profile Plate and Screw System, Arthrex, Inc.
K000684, Small Fragment Dynamic Compression Locking (DCL) System, Synthes (USA)

INDICATIONS FOR USE STATEMENT

The APTUS® Foot 2.8-3.5 System is intended for use in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.

SUBJECT DEVICE DESCRIPTION

The subject device includes: various designs of bone plates (23 plates); wedges and screws for use with various plates for use in performing an opening wedge osteotomy (8 wedges); additional lengths of 3.5 TriLock Screws (locking screws, other lengths cleared in K110908); a new design of 3.5 Cortical Screws (non-locking) in various lengths; and a new design of 4.0 Cancellous Screws in various lengths.

The subject device plates are provided in multiple anatomic designs that vary in length, width, and thickness. The overall dimensions of the plates vary in width from approximately 12 mm to 29 mm, and in length from approximately 25 mm to 92 mm. The plates vary in thickness from 1.6 mm to 2.5 mm.

The subject device plates are used with TriLock locking screws and non-locking screws (cortical and cancellous), including subject device screws and previously cleared Medartis screws. Compatible TriLock locking screws and non-locking cortical screws have a diameter of 2.8 mm and 3.5 mm, and overall lengths ranging from 8 mm to 60 mm. The subject device non-locking cancellous screws have a diameter of 4 mm and overall lengths ranging from 10 mm to 60 mm. The 2.8 Cortical Screws (non-locking), the 3.5 Cortical Screws (non-locking), and the 4.0 Cancellous Screws (non-locking) all have a double-lead thread design. All TriLock Screws (locking) have a double-lead thread design. The subject device plates also are compatible with Medartis K-Wires cleared under K092038.

The subject device screws include screws with the same design as 3.5 TriLock Screws cleared in K110908, with a diameter of 3.5 mm and provided in additional lengths of 10 mm, 12 mm, and 14 mm. The subject device screws also include a new design of 3.5 Cortical Screws provided with a diameter of 3.5 mm and lengths of 10 mm to 60 mm, and a new design of 4.0 Cancellous Screws, with a diameter of 4.0 mm and lengths of 10 mm to 60 mm.

The subject device also includes wedges that are used to support fixation of an opening wedge osteotomy. The wedges are stabilized by corresponding wedge screws that are placed through a plate. The subject device wedges are provided in two size series. The small wedges are 7 mm wide and vary in thickness from 4 mm to 7 mm. The large wedges are 10 mm wide and vary in thickness from 6 mm to 12 mm. The corresponding wedge screws are provided in two sizes: the small wedge screw is used to attach a wedge using an HD7 plate hole (2.8 mm screw hole), and the large wedge screw is to attach a wedge using an HD15 plate hole (3.5 mm screw hole).

The subject device plates, wedges, and screws are manufactured from unalloyed titanium conforming to ASTM F67 or titanium alloy conforming to ASTM F136.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility testing and sterilization validation referenced from K091479, K191848, and K181425; engineering analysis; and cantilever construct fatigue bend testing against the predicate. 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 additional predicate devices 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 additional predicate devices.

The subject device and the primary predicate device, and additional predicate devices have the same intended use for internal fixation of various bones including those of the lower extremity. The Indications for Use Statement (IFUS) for the subject device is similar to that of the primary predicate device K091479.

The differences among the Indications for Use Statements for the subject device and the additional predicate devices (K061808, K052614, and K000684) include language regarding use in fixation of bones locations other than the lower extremity, use in pediatric patients (K061808), or osteopenic bone (K000684). These differences do not impact substantial equivalence because all IFUS express equivalent intended use for internal fixation of various bones including those of the lower extremity.

The plates from the subject device, the primary predicate device K091479, and the additional predicate devices K061808, K052614, and K000684 have the same technological characteristics, have similar design characteristics, screw holes to accommodate locking and non-locking screws, and use the same operating principles for bone fixation. The plates from the subject device, the primary predicate device, and the additional predicate devices encompass a similar range of physical features and dimensions (number of screw holes, overall length, and thickness) but differ slightly.

The additional predicate devices K061808 and K052614 are for support of substantial equivalence of the subject device plate and screw designs, and for comparison in mechanical testing. In comparative testing of plate and screw constructs, the subject device Calcaneus Step Plates, Calcaneus Opening Wedge Plates (with subject device Wedges), Medial Column Plates, and Talonavicular Plates were shown to be substantially equivalent to plates from the additional predicate device K061808. The subject device Cuneiform plates were shown to be substantially equivalent to plates from the additional predicate device K052614. In comparative testing of screws, the subject device 3.5 TriLock Screws and 3.5 Cortical Screws were shown to be substantially equivalent to screws from the additional predicate device K000684, and the subject device 4.0 Cancellous Screws were shown to be substantially equivalent to screws from the additional predicate device K052614.

Differences among the subject device, the primary predicate K051567, and the additional predicate devices (K061808, K052614, and K000684) include the specific plate designs, the specific lengths of screws, and the materials used for manufacturing (K00684 includes screws manufactured from stainless steel). These differences do not impact substantial equivalence in terms of the intended use for internal fixation of the lower extremity.

The plates, wedges, and screws from the subject device are manufactured from unalloyed titanium conforming to ASTM F67 or from titanium alloy material conforming to ASTM F136 identical to these materials used to manufacture the primary predicate device K091479. 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 primary predicate device K091479.

The device-specific instruments are made of stainless steel that is identical to the material used for similar Medartis instruments previously cleared in various submissions including K192297 and K181428. The device-specific accessories have similar designs and are made of the identical materials as the Medartis AG accessory trays included in K192297 and K181425.

Mechanical performance evaluation of the subject device included comparative dynamic testing of worst-case simulated fracture or osteotomy constructs. Mechanical testing of subject device screws was performed according to ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws. Based on the results of the testing, the performance of the subject device was judged to be substantially equivalent to the additional predicate devices K061808, K052614, and K000684.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices 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 K091479 and the additional predicate devices K061808, 052614, and K000684.