November 6, 2020

Medartis AG
% Lauren M. Wessell
RA Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K202589
Trade/Device Name: APTUS Cannulated Compression Screws, APTUS headed Cannulated Compression Screws, APTUS K-Wire System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY, HTN
Dated: September 8, 2020
Received: September 8, 2020

Dear Lauren M. Wessell:

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, MPH
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202589

Device Name
APTUS® Cannulated Compression Screws and APTUS® headed Cannulated Compression Screws

Indications for Use *(Describe)*
APTUS® Cannulated Compression Screws and headed Cannulated Compression Screws are intended for the treatment of fractures, osteotomies and arthrodesis of bones with the appropriate screw size.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202589

Device Name
APTUS® K-Wire System

Indications for Use *(Describe)*
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.

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510(k) Summary

APTUS® headed Cannulated Compression Screws

APTUS® Cannulated Compression Screws

APTUS® K-Wire System

Medartis AG

November 6, 2020

ADMINISTRATIVE INFORMATION

Manufacturer Name	Medartis AG Hochbergerstrasse 60E CH-4057 Basel, Switzerland Telephone: +41 61 633 34 34
Official Contact	Andrea Kiefer-Schweizer Head of Quality Management and Regulatory Affairs
Representative/Consultant	Lauren M. Wessell, RAC 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: lwessell@paxmed.com kthomas@paxmed.com; flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	APTUS® headed Cannulated Compression Screws APTUS® Cannulated Compression Screws APTUS® K-Wire System
Common Name	Screw, Fixation, Bone (Primary) Pin, Fixation, Smooth Washer, Bolt Nut
Regulation Number	21 CFR 888.3040 (Primary) 21 CFR 888.3030
Regulation Name	Smooth or threaded metallic bone fixation fastener (Primary)
Regulatory Class	Class II
Product Code	HWC (Primary), HTY, HTN
Classification Panel	Orthopedic
Reviewing Division	Office of Orthopedic Devices (OHT6) Division of Restorative, Repair and Trauma Devices (DHT6C) Stereotaxic, Bone Growth Stimulators and Fracture Fixation Devices Team

PREDICATE DEVICE INFORMATION

Primary Predicate

K133460, APTUS® Cannulated Compression Screws, Medartis AG

Additional Predicates

K110658, APTUS® Cannulated Compression Screws, Medartis AG
K092038, APTUS® K-Wire System, Medartis AG
K050681, Omnitech System & Easy Lock Osteosystem with Xtremities Plates, TriMed, Inc.
K963192, Synthes Sterile 3.5 mm and 4.0 mm Cannulated Screws, Synthes (USA)

Reference Devices

K193633, APTUS Ankle Trauma System 2.8/3.5, Medartis AG
K191848, APTUS Wrist Spanning Plates 2.5, Medartis AG

INDICATIONS FOR USE STATEMENT

APTUS® Cannulated Compression Screws and headed Cannulated Compression Screws are intended for the treatment of fractures, osteotomies and arthrodesis of bones with the appropriate screw size.

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 APTUS Cannulated Compression Screws in thread diameters 1.7 mm, 2.2 mm, 3.0 mm, 5.0 mm, and 7.0 mm and APTUS headed Cannulated Compression Screws in diameters 2.2 mm, 3.0 mm, 5.0 mm, and 7.0 mm. APTUS Cannulated Compression Screws are headless screws that incorporate threads with different pitch on the head and tip of the screws; this difference in pitch provides compression as the screw is inserted. APTUS headed Cannulated Compression Screws have conventional bone screw heads that apply compression between the threads and the head. Both types of screws provide compression of the bone segments upon insertion of the screw. Additionally, all subject device screws have a triangular SpeedTip® shape designed to improve cutting and insertion torque and an internal hexalobular instrument face.

The APTUS Cannulated Compression Screws and APTUS headed Cannulated Compression Screws come in partially threaded and fully threaded designs. The 1.7 mm diameter screws are provided in overall lengths ranging from 8 mm to 20 mm. The 2.2 mm diameter screw are provided in overall lengths ranging from 10 mm to 40 mm. The 3.0 mm diameter screws are provided in overall lengths ranging from 10 mm to 40 mm. The 4.0 mm diameter screws are provided in overall lengths ranging from 16 mm to 60 mm. The 5.0 mm diameter screws are provided in overall lengths ranging from 24 mm to 70 mm. The 7.0 mm diameter screws are provided in overall lengths ranging from 30 mm to 140 mm.

The subject device 1.7 mm, 2.2 mm, 3.0 mm, 4.0 mm, 5.0 mm, and 7.0 mm thread diameter APTUS Cannulated Compression Screws and APTUS headed Cannulated Compression screws are used with the corresponding subject device K-wires (0.6, 0.8, 1.1, 1.25, 1.6, and 2.2 mm, respectively). The subject device screws also are compatible with the Medartis K-wires cleared under K092038. Similarly, the subject device K-wires are compatible with the APTUS Cannulated Compression Screws cleared under K133460 and K110658.

This submission also includes the corresponding washers for APTUS headed Cannulated Compression Screws.

The subject device cannulated compression screws and washers are manufactured from titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*. The subject device K-wires are manufactured from stainless steel conforming to ASTM F138 *Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).*

All subject devices are provided non-sterile or sterile to the end user. The subject devices are single-use only.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility referenced from K133460, K110658, K092038, and K193633; moist heat sterilization (to be performed by the end user) also referenced from K133460, K110658, K092038, and K193633; X-ray beam sterilization, packaging, and sterile barrier shelf life referenced from K191848 and K193633; and mechanical testing according to ASTM F543 *Standard Specification and Test Methods for Metallic Medical Bone Screws*. Clinical data were not provided in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject devices are substantially equivalent in indications and design principles to the primary predicate device and the additional predicates devices listed above. Additionally, the subject devices have similar technological characteristics as the reference devices.

The subject device APTUS Cannulated Compression Screws and APTUS headed Cannulated Compression Screws have similar Indications for Use Statements (IFUS) to those of devices previously cleared in K133460, K110658, K050681, and K963192. Differences among the IFUS include specific language not in the subject device IFUS: children and adolescent patient populations (K963192), specific anatomical locations (K050681), and references to “small bones” (K050681 and K963192). These differences do not impact the substantial equivalence because all IFUS express equivalent intended use for the treatment of fractures, osteotomies and arthrodesis of bones.

The primary predicate K133460, and additional predicates K110658 and K092038, are in support of substantial equivalence in terms of comparable cannulated compression screw and K-wire designs, compatible cannulated compression screws and K-wires, and identical materials (titanium alloy conforming to ASTM F136 and stainless steel conforming to ASTM F138).

Additional predicate devices K050681 and K963192 are in support of substantial equivalence in terms of comparable screw designs and for comparative mechanical properties.

The reference device K193633 is in support of substantial equivalence for comparable washer designs and identical material (titanium alloy conforming to ASTM F136). Furthermore, the device-specific accessories and Class I instruments have similar designs and are made of identical materials as the Class II accessories and instruments previously cleared in K193633.

The reference devices K191848 and K193633 are in support of substantial equivalence for terminal sterilization and shelf life for product provided sterile to the end user. Additionally, reference devices K191848 and K193633 are in support of identical materials for Class II device-specific accessories and Class I instruments supplied non-sterile to the end-user

CONCLUSION

The subject devices, the primary predicate device, and the additional predicate devices have the same intended use and similar technological characteristics. They encompass a similar range of physical dimensions, are manufactured from the same materials, and are to be sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.