November 3, 2023

Medartis AG
Claudia Santis
Head of Regulatory Affairs
Hochbergerstrasse 60E
Basel, Basel-Stadt CH-4057
Switzerland

Re: K232251
Trade/Device Name: APTUS Cannulated Compression Screws Line Extension, APTUS K-Wire System Line Extension
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: July 28, 2023
Received: July 28, 2023

Dear Claudia Santis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232251

Device Name

APTUS® Cannulated Compression Screws Line Extension

Indications for Use *(Describe)*

APTUS® Cannulated Compression Screws and headed Cannulated Compression Screws are indicated for the treatment of fractures, osteotomies and arthrodesis of bones with the appropriate screw size in the shoulder, elbow, wrist, hand, knee, and the foot and ankle.

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:

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*

K232251

Device Name

APTUS® K-Wire System Line Extension

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® Cannulated Compression Screws Line Extension
APTUS® K-wire System Line Extension
October 5, 2023

ADMINISTRATIVE INFORMATION

Manufacturer Name	Medartis AG Hochbergerstrasse 60E CH-4057 Basel, Switzerland Telephone: +41 61 633 34 34
Official Contact	Claudia De Santis Head Regulatory Affairs Email: claudia.desantis@medartis.com Telephone: +41 79 883 52 88
Additional correspondent	Salvatore Risoli Senior Regulatory Affairs Manager Email: salvatore.risoli@medartis.com Telephone: +41 61 633 37 72

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	APTUS® Cannulated Compression Screws Line Extension APTUS® K-Wire System Line Extension
Common Name	Screw, Fixation, Bone (Primary) Pin, Fixation, Smooth
Regulation Number	21 CFR 888.3040 (Primary) 21 CFR 888.3030
Regulation Name	Smooth Or Threaded Metallic Bone Fixation Fastener (Primary) Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	Class II
Product Codes	HWC (Primary) HTY
Classification Panel	Orthopedic

Applicable, recognized standards used in the non-clinical performance data of the subject device:

- Non-Clinical Performance Testing
  - FDA Guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway"
  - ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws
  - ASTM F1839-08(2021) Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments
- Materials
  - ASTM F67-13 (2013/R2017) Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F138-19 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

PREDICATE DEVICE INFORMATION
Primary Predicate Device
K202589, APTUS® headed Cannulated Compression Screws, APTUS® Cannulated Compression Screws, APTUS® K-Wire System, Medartis AG

Additional Predicate Devices
K133460, APTUS Cannulated Compression Screws 5.0,7.0, Medartis AG
K110658, APTUS® Cannulated Compression Screws, Medartis AG
K092038, APTUS® K-Wire System, Medartis AG
K230971, APTUS 3.5 TriLock Straight Plates, Medartis AG
K963192, Synthes Sterile 3.5 mm and 4.0 mm Cannulated Screws, Synthese (USA)

INDICATIONS FOR USE STATEMENT
APTUS® Cannulated Compression Screws and headed Cannulated Compression Screws are indicated for the treatment of fractures, osteotomies and arthrodesis of bones with the appropriate screw size in the shoulder, elbow, wrist, hand, knee, and the foot and ankle.

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 purpose of this submission is to obtain marketing clearance for APTUS® Cannulated Compression Screw, and APTUS® K-Wire System designs to expand the range of Medartis APTUS fixation devices previously cleared in K133460, K110658, K092038 and K202589.

This submission includes for APTUS® Cannulated Compression Screws (non-sterile and sterile):
- additional thread lengths for previously cleared thread diameters (2.2 mm, 3.0 mm, and 4.0 mm)
- fully threaded screws for two previously cleared thread diameters (2.2 mm and 3.0 mm)

Additionally, the purpose of this submission is to obtain marketing clearance for various APTUS® K-wire designs (non-sterile and sterile) to expand the range of the Medartis APTUS® K-Wire System, previously cleared in K092038, K133460 and K202589, to include longer versions in two (2) diameters (0.8, 1.1 mm). The K-wires are compatible with the subject device cannulated compression screws and APTUS® Cannulated Compression Screws previously cleared in K110658, K133460 and K202589.

All subject device cannulated compression screws are manufactured from titanium alloy conforming to ASTM F136, Standard Specification for Wrought Titanium-6Aluminum- 4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401), the same material for screws previously cleared in K110658, K133460 and K202589.
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), the same material for K-wires previously cleared in K092038, K133460 and K202589.

PERFORMANCE DATA
Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: Mechanical testing according to ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws,* ASTM F1839-08(2021) *Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments* and FDA Guidance *"Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for*

Safety and Performance Based Pathway". Based on the results of the testing, the performance of the subject device was judged to be substantially equivalent to the predicate devices K202589, K110658 and K963192. Clinical data were not provided in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device APTUS® Cannulated Compression Screws have similar designs to those cleared under K202589, K133460 and K110658. Additional lengths of APTUS® Cannulated Compression Screw thread diameters 2.2 mm, 3.0 mm and 4.0 mm as well as fully threaded versions for thread diameters 2.2 and 3.0 mm are subject devices of this submission. The subject device overall lengths and thread lengths are greater for the 2.2, 3.0 and 4.0 mm screws than those of devices previously cleared in K110658 and K202589. The subject device overall lengths are shorter and relative to those of devices previously cleared in K133460. However, the thread geometries are independent of length and, therefore, equivalent to the previously cleared APTUS® Cannulated Compression Screws in K110658, K133460 and K202589. The tip of the APTUS® Cannulated Compression Screws have a triangular SpeedTip® shape designed to improve cutting and reduce insertion torque. All cannulated compression screws have an internal hexalobular instrument interface. These features are equivalent to the devices previously cleared in K110658, K133460 and K202589.

The subject devices APTUS® Cannulated Compression Screws are compatible with the subject device K-wires and Medartis K-wires previously cleared in K202589, K092038 and K133460. Additionally, the subject device K-wires are compatible with the APTUS® Cannulated Compression Screws previously cleared in K202589, K133460 and K110658.

The subject device K-wires have similar designs and dimensions to those of devices cleared in K202589, K133460 and K092038. The predicate K-wires with a diameter of 0.8 mm and 1.1 mm have an overall length of 100 mm. They are provided with either a single-ended trocar (A-5040.xx), single-ended bayonet (lancet) (A-5042.xx), or double-ended trocar (A-5043.xx) tips. The subject K-wires with a diameter of 0.8 mm and 1.1 mm have an overall length of 150 mm. They are provided with a single-ended trocar (A -5040.x1) tip. All subject device K-wires are manufactured from identical stainless-steel conforming to ASTM F138 as the K-wires cleared in K202589, K133460 and K092038.

The subject device includes components provided non-sterile in the same packaging and sterilized to a sterility assurance level (SAL) of 10-6 by the end user using the same sterilization method (moist heat) and parameters as devices previously cleared in K202589, K133460, K110658, and K092038. Additionally, the subject device includes components provided sterile to the end user in the same packaging that are terminally sterilized to an SAL of 10-6 using the same sterilization method (X-ray beam irradiation) as the primary predicate K202589. For both sterilization validations, the subject devices do not represent a new worst-case.

All subject device cannulated compression screws, K-wires and accessories are manufactured in the same facilities using the same materials and manufacturing processes as used for the Medartis APTUS® devices previously cleared in predicates K202589, K110658, K133460, and K092038. Therefore, no new biocompatibility testing has been performed, as the subject device is substantially equivalent to these devices regarding materials and processing.

CONCLUSION

Overall, the subject device has the following similarities to the predicate devices:

- has the similar intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has similar packaging and is sterilized or is to be end-user sterilized using the same materials and processes.

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