June 2, 2023

Medartis AG
% Kevin Thomas, Phd
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K230971
Trade/Device Name: APTUS® 3.5 TriLock Straight Plates
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: April 3, 2023
Received: April 5, 2023

Dear Dr. 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 -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6B: 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)*
K230971

Device Name

APTUS 3.5 TriLock Straight Plates

Indications for Use *(Describe)*

The APTUS 3.5 TriLock Straight Plates are intended for the fixation of fractures, osteotomies and non-unions of the scapula, olecranon, radius, ulna, foot, distal tibia and fibula.

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 3.5 TriLock Straight Plates

April 3, 2022

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS 3.5 TriLock Straight Plates
Common Name	Plate, fixation, bone
Regulation Number	21 CFR 888.3030
Regulation Name	Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	Class II
Product Code	HRS
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
K193633, APTUS® Ankle Trauma System 2.8/3.5, Medartis AG

Additional Predicate Devices
K082807, Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications, Synthes (USA)
K011335, Synthes One-Third Tubular DCL Plate, Synthes (USA)
K110908, APTUS® Foot 3.5 System, Medartis AG
K193639, APTUS® Foot 2.8-3.5 System, Medartis AG

The APTUS 3.5 TriLock Straight Plates are intended for the fixation of fractures, osteotomies and non-unions of the scapula, olecranon, radius, ulna, foot, distal tibia and fibula.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for additional plate designs to expand the range of the Medartis APTUS® Ankle Trauma System 2.8/3.5, previously cleared under K193633. The subject device APTUS 3.5 TriLock Straight Plates are available in eleven (11) designs with 2, 3, 4, 5, 6, 7, 8, 10, 12, 14, or 16 screw holes. The plates have an overall length ranging from 32 mm to 200 mm. The subject device plates include screw holes designed to accommodate appropriately sized bone screws and K-wires presently marketed as part of the APTUS System. The subject device plates are compatible with screws and K-wires previously cleared in K193633, K110908, and K092038.

The subject device plates are manufactured from titanium alloy conforming to ASTM F136, and are provided non-sterile or sterile to the end user.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility referenced from K193633; moist heat sterilization (to be performed by the end user) referenced from K193633; X-ray beam sterilization, packaging, and sterile barrier shelf life referenced from K193633; and mechanical testing according to ASTM F382. Clinical data were not provided in this submission.

EQUIVALENCE TO MARKETED DEVICES

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 are tables comparing the Indications for Use Statements (IFUS) and the technological characteristics of the subject device, the primary predicate device, and the additional predicate devices.

The Indications for Use Statements (IFUS) for the subject device and the predicate devices listed above include language for fixation of fractures, osteotomies, and non-unions of various bones. The IFUS for the predicate devices K110908 and K193639 do not reference non-unions. The IFUS for the subject device and predicate device K193639 include language that includes use in the foot. The IFUS for the additional predicate devices K082807 and K011335 include language referring to fixation of the pelvis that is not relevant to the subject device. The IFUS for K082807 and K011335 also include language referring to use in osteopenic bone; this language is not included in the IFUS for the subject device. Additionally, the IFUS of the subject device does not list specifically adult patients and pediatric patients as in the predicate device K082807. These minor differences among the IFUS do not impact substantial equivalence because all IFUS express equivalent intended use for internal fixation of bones in various anatomic locations.

The primary predicate K193633 is in support of substantial equivalence in terms of similar plate designs; compatible screw designs; identical plate materials; identical materials for the device-specific (Class II) instruments and accessories; the same sterilization, packaging, and shelf life for product provided sterile to the end user; and the same sterilization for devices provided non-sterile to the end user.

The plates from the subject device and the primary predicate device K193633 and the additional predicate device K082807 have the same technological characteristics, have similar design characteristics, and include screw holes to accommodate locking and non-locking screws.

The subject device plates are compatible with Medartis screws previously cleared in K193633 and K110908, including 3.5 TriLock (locking) and cortical (non-locking) screws. The subject device plates also are compatible with Medartis K-Wires previously cleared in K092038, K193633, and K193639.

K082807 and K011335 are in support of substantial equivalence in terms of similar Indications for Use, comparable plate designs (use with locking and non-locking screws), and a similar range of physical dimensions (overall width, overall length). K011335 is also in support of substantial equivalence in terms of comparative mechanical testing.

All subject device final finished components (plates, device-specific instrument templates, and device-specific accessories) are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the primary predicate device K193633, and therefore, are substantially equivalent to these previously-cleared devices regarding biocompatibility.

The subject device components that are provided sterile to the end user are packaged using the same materials, are sterilized by the same method, and have the same sterile barrier shelf life as the Medartis devices in K193633. The subject device components that are provided non-sterile also are packaged using the same materials, and are to be sterilized by the same methods as the Medartis devices in K193633.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility referenced from K193633; moist heat sterilization (to be performed by the end user) referenced from K193633; X-ray beam sterilization, packaging, and sterile barrier shelf life referenced from K193633; and mechanical testing according to ASTM F382.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device, the primary predicate, and the additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

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

Substantial Equivalence – Indications for Use Statements

	Indications for Use Statement
Subject Device	
APTUS 3.5 TriLock Straight Plates Medartis AG	The APTUS 3.5 TriLock Straight Plates are intended for the fixation of fractures, osteotomies and non-unions of the scapula, olecranon, radius, ulna, foot, distal tibia and fibula.
Primary Predicate Device	
K193633 APTUS® Ankle Trauma System 2.8/3.5 Medartis AG	APTUS® Ankle Trauma System 2.8/3.5 is indicated for fractures, osteotomies, malunions and non-unions of the distal tibia and fibula.
Additional Predicate Devices	
K082807 Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications Synthes (USA)	Synthes 3.5 mm Locking Compression Plate (LCP) System: The Synthes 3.5 mm Locking Compression Plate (LCP) System is indicated for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone for adult patients. These plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients. Synthes 4.5 mm Locking Compression Plate (LCP) System: The Synthes 4.5 mm Locking Compression Plate (LCP) System is indicated for fixation of various long bones, such as the humerus, femur and tibia and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients. These plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones. in pediatric patients.
K011335 Synthes One-Third Tubular DCL Plate Synthes (USA)	Synthes One-Third Tubular Plate is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone as a part of the Synthes Small Fragment DCL System.
K110908 APTUS® Foot 3.5 System Medartis AG	The APTUS® Foot 3.5 System is indicated for fractures and osteotomies of the calcaneus.
K193639 APTUS® Foot 2.8-3.5 System Medartis AG	The APTUS® Foot System is intended for use in small bones, in particular in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.

Substantial Equivalence – Technological Characteristics

Features / Comparisons	Subject Device	Primary Predicate Device	Additional Predicate Device	Additional Predicate Device	Additional Predicate Device	Additional Predicate Device
		K193633	K082807	K011335	K110908	K193639
	APTUS 3.5 TriLock Straight Plates	APTUS® Ankle Trauma System 2.8/3.5	Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications	Synthes One-Third Tubular DCL Plate	APTUS® Foot 3.5 System	APTUS® Foot 2.8-3.5 System
	Medartis AG	Medartis AG	Synthes (USA)	Synthes (USA)	Medartis AG	Medartis AG
Product Code	HRS	HRS, HWC, HTN	HRS, HWC	HRS	HRS, HWC	HRS, HWC, PLF
Reason for Predicate/Reference Device	Not applicable	Similar intended use and IFUS; Plate designs, including use with locking and non-locking screws; 3.5 compatible screws; compatible K-wires; identical materials; moist heat sterilization (by end user); x-ray beam sterilization, packaging, sterile barrier shelf life; biocompatibility	Similar intended use and IFUS; Plate designs, including use with locking and non-locking screws; similar range of plate dimensions; similar material;	Similar intended use and IFUS; Plate designs, including use with locking and non-locking screws; similar range of plate dimensions; similar material; comparison mechanical testing	Similar intended use and IFUS; Plate designs, including use with locking and non-locking screws; 3.5 compatible screws	Similar intended use and IFUS; Plate designs, including use with locking and non-locking screws; 3.5 compatible screws
Plate Description	Straight plates with 3.5 TriLock locking; scalloped edge design; rounded ends; 11 sizes	Anatomic plate designs; Multiple designs and sizes; Screw holes accommodate 3.5 TriLock (locking) and non-locking (cortex) screws	Straight plates with locking holes; LCP fixed-angle locking holes; 9 sizes	Locking technology; LCP fixed-angle locking holes	Anatomic plate designs; Multiple designs and sizes; Screw holes accommodate 3.5 TriLock (locking) and non-locking (cortex) screws	Anatomic plate designs; Multiple designs and sizes; Screw holes accommodate 3.5 TriLock (locking) and non-locking (cortex) screws
						
Plate Materials	Ti-6Al-4V alloy, ASTM F136	Ti-6Al-4V alloy, ASTM F136 Unalloyed titanium, ASTM F67	Stainless steel, commercially pure titanium	Stainless steel, commercially pure titanium	Unalloyed titanium, ASTM F67	Ti-6Al-4V alloy, ASTM F136 Unalloyed titanium, ASTM F67
Screw Holes	2, 3, 4, 5, 6, 7, 8, 10, 12, 14, and 16 holes	Various, 7 – 24 holes	3, 4, 5, 6, 7, 8, 9, 10, and 12 holes	Various, 2-12 holes	12 or 13 holes	Various
Plate Thickness	2, 3, and 4 hole plates: 2.4 mm 5-16 hole plates: 2.2. mm	Various thicknesses, 1.6 mm – 30.5 mm	1 mm	*Not provided in 510(k) Summary*	1.4 mm to 2.0 mm	1.6 mm to 2.5 mm
Plate Lengths	Various lengths, 32 mm – 200 mm	Various lengths, 50 mm – 260 mm	3-10 hole plates: 33 mm – 117 mm 12 hole plates: 141 mm	28 mm -148 mm	Various overall dimensions	Various lengths, 25 mm to 92 mm
Plate Width	10.2 mm in the widest part	Various widths	9.8 mm	*Not provided in 510(k) Summary*	Various overall dimensions	Various widths, 12 mm to 29 mm
Sterility	Provided non-sterile and sterile	Provided non-sterile and sterile	*Not provided in 510(k) Summary*	Provided non-sterile and sterile	Provided non-sterile	Provided non-sterile
Sterilization	Non-sterile: to be sterilized by moist heat Sterile: X-ray beam sterilization	Non-sterile: to be sterilized by moist heat Sterile: X-ray beam sterilization	*Not provided in 510(k) Summary*	*Not provided in 510(k) Summary*	Non-sterile: to be sterilized by moist heat	Non-sterile: to be sterilized by moist heat