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: K193633
Trade/Device Name: APTUS® Ankle Trauma System 2.8/3.5
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, HTN
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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193633

Device Name

APTUS® Ankle Trauma System 2.8/3.5

Indications for Use *(Describe)*

APTUS® Ankle Trauma System 2.8/3.5 is indicated for fractures, osteotomies, malunions and non-unions of the 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

K193633

Medartis AG

APTUS® Ankle Trauma System 2.8/3.5

February 24, 2020

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Ankle Trauma System 2.8/3.5
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
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
K013248, Synthes (USA) LCP Distal Tibia Plates, Synthes (USA)

Additional Predicate Devices
K092812, Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates, Synthes (USA)
K011335, Synthes One-third Tubular DCL Plate, Synthes (USA)
K083213, Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates, Synthes (USA)
K000684, Small Fragment Dynamic Compression Locking (DCL) System, Synthes (USA)
K091479, APTUS® Foot System, Medartis AG

Reference Devices
K103332, APTUS® Ulna Plates, Medartis AG
K192297. APTUS® Wrist Arthrodesis Plates, Medartis AG
K191848, APTUS® Wrist Spanning Plates 2.5, Medartis AG.

INDICATIONS FOR USE STATEMENT

APTUS® Ankle Trauma System 2.8/3.5 is indicated for fractures, osteotomies, malunions and non-unions of the distal tibia and fibula.

SUBJECT DEVICE DESCRIPTION

The subject device includes: includes various designs for internal fixation of the distal tibia and distal fibula; 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 concave washer for use with Medartis 3.5 Cortical Screws.

The subject device plates are provided in multiple anatomic designs that vary in length, width, and thickness. The plat designs include: 3.5 TriLock Distal Tibia L Plates and T Plates; 2.8/3.5 TriLock Distal Tibia Plates Medial; 2.8/3.5 TriLock Distal Tibia Plates Anterolateral; 2.8/3.5 TriLock Distal Fibula Plates Lateral, with and without Flap; 2.8 TriLock Distal Fibula Plates Crossed; and 2.8 TriLock Distal Fibula Plates Straight.

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 2.8 Cortical Screws (non-locking) and 3.5 Cortical Screws (non-locking) 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 in 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.

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

The subject device components 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 K091479, K103332, K192297, and K191848; moist heat sterilization (to be performed by the end user) also referenced from K091479, K103332, K192297, and K191848; X-ray beam sterilization, packaging, and sterile barrier shelf life referenced from K191848; engineering analysis; and mechanical testing according to ASTM F382 and ASTM F543. 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, the additional predicate devices, and the reference 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, the additional predicate devices, and the reference devices.

The primary predicate device K013248 is in support of substantial equivalence in terms of comparable IFUS, plate designs (including use with locking and non-locking screws), screw designs, and materials. The primary predicate device K013248 also is in support of substantial equivalence in terms of comparison mechanical testing.

The additional predicate devices K092812, K011335, K083213, K000684 are in support of substantial equivalence in terms of comparable plate designs (including use with locking and non-locking screws), and for comparative mechanical testing.

The additional predicate device K091479 is in support of substantial equivalence in terms of comparable plate designs (including use with locking and non-locking screws), compatible screws and screw designs, and identical materials (unalloyed titanium conforming to ASTM F67 and titanium alloy conforming to ASTM F136).

The reference device K103332 is in support of substantial equivalence in terms of comparison mechanical testing.

The reference device K192297 is in support of substantial equivalence in terms of identical plate material (ASTM F67), and identical materials for the Class II accessories and instruments.

The reference device K191848 is in support of substantial equivalence in terms of identical plate material (ASTM F136), and for sterilization and shelf life for product provided sterile to the end user.

The subject device, the primary predicate device, the additional predicate devices, and the reference devices have the same intended use for internal fixation of bones including the lower extremity. The IFUS for K013248, K092812, K083213, K000684 include specific language referencing the tibia, fibula, or both.

Differences among the IFUS for the subject device, the primary predicate device, the additional predicate devices, and the reference devices include specific language not in the subject device IFUS referring to internal fixation of bones other than the lower extremity, or the use in osteopenic bone (K013248, K092812, K083213, K000684). The IFUS for the reference devices K103332, K192297, and K191848 include language referring to internal fixation of the upper extremity. These minor differences do not impact substantial equivalence because all IFUS express equivalent intended use for internal fixation of various bones.

The plates from the subject device and the plates cleared in K091479, K103332, K192297, and K191848 have the same technological characteristics, have similar design characteristics, include screw holes to accommodate locking and non-locking screws, and are made of identical materials.

The plates from the subject device, the primary predicate device K013248, and the additional predicate devices K092812, K011335, K083213, and K000684 have similar designs for specific anatomic locations and encompass a similar range of physical dimensions (overall width, overall length, and thickness).

The plates from the subject device are compatible with subject device screws and with Medartis AG screws cleared in K091479, and also are compatible with Medartis AG K-Wires cleared in K092038.

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 Medartis AG devices cleared in K091479, K103332, K192297, and K191848, and, therefore, are substantially equivalent to these devices regarding biocompatibility.

The subject device includes components that are provided non-sterile and components that are provided sterile. The subject device components that are provided non-sterile are packaged using the same materials, and are to be sterilized by the same methods as the Medartis AG devices cleared in K091479, K103332, and K192297. The subject device components that are provided sterile to the end user are packaged using the same materials, are to be sterilized by the same method, and have the same sterile barrier shelf life as the Medartis AG devices cleared in K191848.

The differences among the plates from the subject device, the primary predicate device, the additional predicate devices, and the reference devices include variations in the designs of the plates (number of designs, overall dimensions, placement of screw holes), and variations in the sizes of the compatible screws. The plates from the primary predicate device K013248 and from the additional predicate devices K092812, K011335, K083213, and K000684 are made of a different titanium alloy material compared to the subject device. These slight differences among the subject device, the primary predicate, and reference devices do not impact safety or effectiveness.

The subject device screws have similar designs and are made of the identical material as the Medartis AG devices cleared in K091479 and K103332.

The subject device washer is made of the identical titanium alloy conforming to ASTM F136 as the subject device plates and screws and has a design similar to the Medartis AG washers cleared in K112560.

The subject device Class II accessories (trays and device-specific instruments) have similar designs and are made of identical materials as the Medartis AG Class II accessories and instruments previously cleared in K192297.

CONCLUSION

The subject device, the primary predicate device, and the reference device 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, the additional predicate devices, and the reference devices listed above.

Substantial Equivalence – Indications for Use Statements

	Indications for Use Statement
Subject 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.
Primary Predicate Device	
K013248 Synthes (USA) LCP Distal Tibia Plates Synthes (USA)	The Synthes Locking Compression Plate (LCP) System 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. The Synthes LCP Distal Tibia Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia and other small bones as a part of the Synthes Small Fragment LCP System.
Additional Predicate Devices	
K092812 Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates Synthes (USA)	Synthes 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates are indicated for fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone.
K011335 Synthes One-third Tubular DCL Plate Synthes (USA)	No 510(k) Summary or Indications for Use Statement are available on the FDA 510(k) database website
K083213 Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates Synthes (USA)	The Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates are indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.
K000684 Small Fragment Dynamic Compression Locking (DCL) System Synthes (USA)	Fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.
K091479 APTUS® Foot 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.
Reference Devices	
K103332 APTUS® Ulna Plates Medartis AG	APTUS® Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.
K192297 APTUS® Wrist Arthrodesis Plates Medartis AG	APTUS® Wrist Arthrodesis Plates are indicated for wrist arthrodesis.
K191848 APTUS® Wrist Spanning Plates 2.5 Medartis AG	APTUS® Wrist Spanning Plates 2.5 are intended for use in forearm fractures.

Substantial Equivalence – Technological Characteristics

Feature	Subject Device	Primary Predicate Device	Additional Predicate Devices	Additional Predicate Device	Reference Device	Reference Device	Reference Device
	K193633 APTUS® Ankle Trauma System 2.8/3.5	**K013248** Synthes (USA) LCP Distal Tibia Plates	**K092812** Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates **K011335** Synthes One-third Tubular DCL Plate **K083213** Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates **K000684** Small Fragment Dynamic Compression Locking (DCL) System	**K091479** APTUS® Foot System	**K103332** APTUS® Ulna Plates	**K192297** APTUS® Wrist Arthrodesis Plates	**K191848** APTUS® Wrist Spanning Plates 2.5
	Medartis AG	Synthes USA	Synthes USA	Medartis AG	Medartis AG	Medartis AG	Medartis AG
Product Code	HRS	HRS	HRS, HWC, KTT	HRS, HWC	HRS, HWC	HRS, HWC	HRS, HWC
Intended Use	Internal fixation of the upper extremity	Internal fixation, including the lower extremity	Internal fixation, including the lower extremity	Internal fixation of the lower extremity	Internal fixation of the upper extremity	Internal fixation of the upper extremity	Internal fixation of the upper extremity
Reason for Predicate/Reference Device	Not applicable	Plate designs, including use with locking and non-locking screws; Comparison mechanical testing	Plate designs, including use with locking and non-locking screws; Comparison mechanical testing	Plate designs, including use with locking and non-locking screws; Compatible screws; Materials ASTM F67 and ASTM F136	Reference device for comparison mechanical testing	Reference device for ASTM F67 material; Reference device for Class II accessory and instrument materials	Reference device for ASTM F136 material; Reference device for sterilization and shelf life for product provided sterile
Plates	Anatomic plate designs Multiple designs and sizes Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs Multiple designs and sizes Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs Multiple designs and sizes Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs Straight, T-Shaped, Grid, Wavy and Wing Multiple designs and sizes Screw holes accommodate locking and non-locking (cortex) screws Various overall dimensions Thickness 1.3 mm to 1.6 mm	Anatomic plate designs Multiple designs and sizes Screw holes accommodate locking and non-locking (cortex) screws Various overall dimensions Widths 7-36 mm Lengths 7-184 mm Thickness 0.6 mm to 3.2 mm		
	2.8/3.5 TriLock Distal Tibia Plates Medial Locking technology - TriLock multidirectional (±15°) and angular stable locking holes (locking / non-locking) - Oblong holes (non-locking) - One compression hole (non-locking) Implant dimensions - Screw holes total: 11, 13, 15, 17, 19, 21, 23, 25 - Left and Right - Plate length: 91-260 mm - Plate thickness: 3.25 mm	**DePuy Synthes 3.5 mm LCP Low Bend Medial Distal Tibia Plate K013248** Locking technology - LCP fixed-angle locking holes - LCP combi-holes (locking / non-locking) Implant dimensions Screw holes in shaft: 4, 6, 8, 10, 12 and 14 hole lengths - Left and Right - Plate length: 109-239 mm - Plate thickness: Not stated					
	2.8/3.5 TriLock Distal Tibia Plates Anterolateral Locking technology - TriLock multidirectional (±15°) and angular stable locking holes (locking / non-locking) - Oblong holes (non-locking) Implant dimensions - Screw holes total: 11, 13, 15, 17, 19, 21, 23, 25 - Left and Right - Plate length: 91-260 mm - Plate thickness: 3.0mm		**DePuy Synthes 3.5 mm LCP Anterolateral Distal Tibia Plate K092812, K000684** Locking technology - LCP fixed-angle locking holes - LCP combi-holes (locking / non-locking) Implant dimensions -Screw holes in shaft: 4, 6, 8, 10, 12 and 14 hole lengths - Left and Right - Plate length: 109-239 mm - Plate thickness: 2.0 mm in the metaphyseal region, 3.6 mm in the diaphyseal region				

Substantial Equivalence – Technological Characteristics

Feature	Subject Device	Primary Predicate Device	Additional Predicate Devices	Additional Predicate Device	Reference Device	Reference Device	Reference Device
	K193633 APTUS® Ankle Trauma System 2.8/3.5	**K013248** Synthes (USA) LCP Distal Tibia Plates	**K092812** Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates **K011335** Synthes One-third Tubular DCL Plate **K083213** Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates **K000684** Small Fragment Dynamic Compression Locking (DCL) System	**K091479** APTUS® Foot System	**K103332** APTUS® Ulna Plates	**K192297** APTUS® Wrist Arthrodesis Plates	**K191848** APTUS® Wrist Spanning Plates 2.5
	Medartis AG	Synthes USA	Synthes USA	Medartis AG	Medartis AG	Medartis AG	Medartis AG
	3.5 TriLock Distal Tibia L Plates and T Plates Locking technology - TriLock multidirectional (±15°) and angular stable locking holes (locking / non-locking) - Oblong holes (non-locking) Implant dimensions - Screw holes total: 7 - Left and Right in L design - Plate lengths: 50 mm - Plate thickness: 2.5 mm		**LCP One-third Tubular Plates 3.5** **K011335** Locking technology - LCP fixed-angle locking holes Implant dimensions - Screw holes: 2-12 holes - Plate length: 28-148 mm - Plate thickness: no information available				
	2.8/3.5 Distal Fibula Plate Lateral with and without Flap Locking technology - TriLock multidirectional (±15°) and angular stable locking holes (locking / non-locking) - Oblong holes (non-locking) Implant dimensions - Screw holes total: 13, 15, 17, 19, and 21 With Flap 14,and 16 -Left and Right - Plate length: 93-192mm - Plate thickness: 2.5 mm		**LCP Distal Fibula Plates** **K083213** Locking technology - LCP fixed-angle locking holes - LCP combi-holes (locking / non-locking) Implant dimensions - Screw holes in shaft 3,4,5,6,7,9,11,13 and 15 - Left and right - Plate thickness: no information available - Plate length: 73-229 mm				
	2.8 Distal Fibula Plate Crossed **2.8 Distal Fibula Plate Straight** Locking technology - TriLock multidirectional (±15°) and angular stable locking holes (locking / non-locking) - Oblong holes (non-locking) Implant dimensions - Screw holes total: 9,11,13,15 and 17 - Plate lengths: 63-119 mm - Plate thickness: 1.6 mm		**LCP One-third Tubular Plates 3.5** **K011335** Locking technology - LCP fixed-angle locking holes Implant dimensions - Screw holes: 2-12 holes - Plate length: 28-148 mm - Plate thickness: no information available				

Substantial Equivalence – Technological Characteristics

Feature	Subject Device	Primary Predicate Device	Additional Predicate Devices	Additional Predicate Device	Reference Device	Reference Device	Reference Device
	K193633 APTUS® Ankle Trauma System 2.8/3.5	**K013248** Synthes (USA) LCP Distal Tibia Plates	**K092812** Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates **K011335** Synthes One-third Tubular DCL Plate **K083213** Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates **K000684** Small Fragment Dynamic Compression Locking (DCL) System	**K091479** APTUS® Foot System	**K103332** APTUS® Ulna Plates	**K192297** APTUS® Wrist Arthrodesis Plates	**K191848** APTUS® Wrist Spanning Plates 2.5
	Medartis AG	Synthes USA	Synthes USA	Medartis AG	Medartis AG	Medartis AG	Medartis AG
Plate Materials	Ti-6Al-4V alloy, ASTM F136	Titanium alloy, Ti-6l-7Nb	Titanium alloy, Ti-6l-7Nb	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67	Ti-6Al-4V alloy, ASTM F136
Screws							
Screw Designs	Subject device screws and previously cleared Medartis APTUS Screws (K091479, K112560, K110908): Locking screws: cortical thread form, double-lead thread, self-tapping, fully threaded Non-locking screws: cortical thread form, single-lead thread, self-tapping, fully threaded	*Compatible screws:* *Locking screws* *- 3.5 mm locking screws, length 10 - 65 mm* *Cortical screws* *- 3.5 mm Cortex screws, length 10 - 60 mm* *Cancellous screws* *- 4.0 mm Cancellous screws, length 10 - 60 mm*	*Compatible screws:* *Locking screws* *- 3.5 mm locking screws, length 10 - 65 mm* *Cortical screws* *- 3.5 mm Cortex screws, length 10 - 60 mm* *Cancellous screws* *- 4.0 mm Cancellous screws, length 10 - 60 mm*	Self-tapping conventional (cortex) and locking	Locking screws: Cortical thread form, double-lead thread, self-drilling, self-tapping, fully threaded Non-locking screws: Cortical thread form, single-lead thread, self-drilling, self-tapping, fully threaded *Previously cleared Medartis APTUS Screws (K051567, K103332):* *Locking screws:* *Cortical thread form, double-lead thread, self-tapping, fully threaded* *Non-locking screws:* *Cortical thread form, single-lead thread, self-tapping, fully threaded*		
Screw Diameters	Subject device screws: 3.5 mm locking and non-locking *Previously cleared:* *2.8 mm (locking and non-locking)* *3.5 locking*	*Locking screws: 2.3, 2.7, 3.5 mm* *Cortical screws: 2.3, 2.7, 3.0, 3.5 mm* *Cancellous screws: 4.0 mm*	*Locking screws: 2.3, 2.7, 3.5 mm* *Cortical screws: 2.3, 2.7, 3.0, 3.5 mm* *Cancellous screws: 4.0 mm*	2.0 to 2.8 mm	Locking screws: 2.5 mm Cortical screws: 1.5 mm, 2.5 mm *Previously cleared:* *1.5 mm and 2.5 mm*		
Screw Lengths	Subject device screws: 3.5 mm locking: 10 mm to 14 mm 3.5 mm non-locking: 10 mm to 60 mm *Previously cleared:* *2.8 mm locking:8 mm to 60 mm* *2.8 mm non-locking): 8 mm to 60 mm* *3.5 mm locking:16 mm to 60 mm*	*Locking screws* *8-26 mm (2.3 diameter)* *8-65 mm (2.7 diameter)* *6-65 mm (3.5 mm diameter)* *Cortical screw* *8-26 mm (2.3 diameter);* *8-65 mm (2.7 diameter)* *8-26 mm (3.0 diameter);* *6-65 mm(3.5 mm diameter)* *Cancellous screws* *12-60 mm (4.0 mm diameter)*	*Locking screws* *8-26 mm (2.3 diameter)* *8-65 mm (2.7 diameter)* *6-65 mm (3.5 mm diameter)* *Cortical screw* *8-26 mm (2.3 diameter);* *8-65 mm (2.7 diameter)* *8-26 mm (3.0 diameter);* *6-65 mm(3.5 mm diameter)* *Cancellous screws* *12-60 mm (4.0 mm diameter)*	8 to 45 mm	Locking screws: 8 mm to 24 mm Cortical screws: 1.5 mm Ø, 8 mm to 15 mm 2.5 mm Ø, 8 mm to 24 mm *Previously cleared:* *Various lengths*		
Screw Materials	Subject device and previously cleared screws: Ti-6Al-4V alloy, ASTM F136	*Compatible screws:* *Ti-6Al-4V alloy, ASTM F136; Stainless steel*	*Compatible screws:* *Ti-6Al-4V alloy, ASTM F136; Stainless steel*	Ti-6Al-4V alloy, ASTM F136	Ti-6Al-4V alloy, ASTM F136	*Previously cleared:* *Ti-6Al-4V alloy, ASTM F136*	*Previously cleared:* *Ti-6Al-4V alloy, ASTM F136*
How Provided							
Sterility	Provided non-sterile and Provided sterile	Provided non-sterile and Provided sterile	Provided non-sterile and Provided sterile	Provided non-sterile	Provided non-sterile	Provided non-sterile	Provided sterile
Sterilization	Non-sterile: to be sterilized by moist heat Sterile: X-ray beam irradiation	Non-sterile: to be sterilized by moist heat Sterile: method not stated	Non-sterile: to be sterilized by moist heat Sterile: method not stated	To be sterilized by moist heat	To be sterilized by moist heat	To be sterilized by moist heat	X-ray beam irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use