January 24, 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: K192984
Trade/Device Name: APTUS Clavicle 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
Dated: October 25, 2019
Received: October 25, 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)*

K192984

Device Name

APTUS® Clavicle System

Indications for Use *(Describe)*

APTUS® Clavicle System is indicated for treatment of fractures, osteotomies, malunions and non-unions of the clavicle.

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
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

K192984

Medartis AG

APTUS® Clavicle System

January 8, 2020

ADMINISTRATIVE INFORMATION

Manufacturer Name	Medartis AG Hochbergerstrasse 60E CH-4057 Basel, Switzerland Telephone: +41 61 633 34 34 Fax: +41 61 633 34 00
Official Contact	Andrea Kiefer-Schweizer Head of Quality Management and Regulatory Affairs
Representative/Consultant	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: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	APTUS® Clavicle 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
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
K111540, Synthes 3.5 mm LCP Clavicle Plate System, Synthes (USA)

Other Predicate Devices
K073186, Synthes 3.5 mm LCP Clavicle Plate System, Synthes (USA)
K101536, 2.7/3.5 mm VA-LCP Anterior Clavicle Plate System, Synthes (USA)
K112111, Acu-Sinch Repair System, Acumed LLC

Reference Devices
K110176, AxSOS® Locked Plating System Line Extension of 4 mm Locking Inserts, Howmedica Osteonics Corp.
K191848, APTUS® Wrist 2.5 System, Medartis AG
K181425, APTUS® Proximal Humerus System, Medartis AG

INDICATIONS FOR USE STATEMENT

APTUS® Clavicle System is indicated for treatment of fractures, osteotomies, malunions and non-unions of the clavicle.

SUBJECT DEVICE DESCRIPTION

This submission includes a total of 22 bone plates for internal fixation of the clavicle.

Superior Lateral Plates are provided in 12-hole and 14-hole designs for the left and right clavicle, with pre-bent flaps that allow for additional anteroposterior screw fixation. The Superior Lateral Plates include an oblong hole in the plate for an optional plate insert that is provided in two (2) designs: one insert design is for suture fixation of the coracoclavicular ligament, and one insert design is for placement of an additional cortical screw. The Superior Lateral Plates have a curved shape, a maximum thickness of 3.4 mm, and an overall length between approximately 78 mm and 100 mm.

Superior Lateral Shaft Plates are provided in an 11-hole design for the left and right clavicle. The Superior Lateral Shaft Plates are designed for stable fixation of fractures on the lateral third of the midshaft without compromising the capsule and the acromioclavicular (AC) joint. The Superior Lateral Shaft Plates have a curved shape, a maximum thickness of 3.4 mm, and an overall length of approximately 94 mm.

Superior Midshaft Plates are provided in 6-hole, 8-hole, 10-hole, and 12-hole designs for the left and right clavicle. The 8-hole plates are provided with three (3) different S-shaped curvatures. The plates have a maximum thickness of 3.4 mm and an overall length between approximately 84 mm and approximately 141 mm.

Anterior Midshaft Plates are provided in 6-hole, 8-hole, and 10-hole designs for midshaft fractures of the clavicle. The Anterior Midshaft plates are designed for use on either the left or right clavicle. The plates have a maximum thickness of 3.4 mm, and an overall length between approximately 8 mm and approximately 118 mm.

The Anterior Lateral Plate is provided in a 6-hole design for lateral fractures of the left or right clavicle. The plate has a maximum thickness of 3.4 mm, and an overall length of approximately 80 mm.

All of the subject device plates and the plate inserts for the Superior Lateral Plates are manufactured from titanium alloy conforming to ASTM F136.

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 compatible screws are 2.8 mm in diameter and were previously cleared in K091479 and K103332. The subject device plates also are compatible with 1.6 mm diameter Medartis APTUS® K-Wires previously cleared in K092038.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility testing and sterilization validation referenced from K191848 and K181425; engineering analysis; static tensile testing of suture-suture insert-plate constructs and static tensile testing of suture-simulated clavicle bone constructs; and comparative dynamic mechanical testing in a simulated fracture model. 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, the other 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 other predicate devices, and the reference devices.

The subject device, the primary predicate device, the other predicate devices, and the reference devices have the same intended use for internal fixation of the bones of the upper extremity and lower extremity (K110176). The Indications for Use Statement for the subject device is very similar to the Indications for Use Statement for K073186; the minor differences in language do not impact substantial equivalence.

The differences among the Indications for Use Statements for the subject device, the primary predicate (K111540), the other predicate devices (K101536, K112111), and the reference devices (K110176, K191848, K181425) include language regarding: use in adults and adolescents (K111540, K101536); use in specific procedures (K112111); use in fixation of the lower extremity (K110176); use in fixation of the forearm (K191848); and use in fixation of the proximal humerus (K181425). These differences do not impact substantial equivalence because all IFUS express equivalent intended use for internal fixation of the bones of the upper extremity or lower extremity, and the devices are included to support substantial equivalence as described in this section.

The plates from the subject device, the primary predicate device (K111540), the other predicate devices (K073186, K101536, K112111), and the reference devices (K110176, K191848, K181425) 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 (K111540), and the other predicate devices (K073186, K101536, K112111) include similar anatomic designs for superior or anterior surgical placement on the clavicle. The plates from the subject device, the primary predicate (K111540), and the other predicate devices K073186 and K101536 encompass a similar range of physical features and dimensions (number of screw holes, overall length, and thickness).

The other predicate device K112111 is for support of substantial equivalence of the subject device Insert for Suture Fixation. The Acu-Sinch insert (K112111) and the subject device Insert for Suture Fixation have similar design features and are made of the same or similar materials (titanium alloy or unalloyed titanium). The differences between the subject device Insert for Suture Fixation and the Acu-Sinch insert include the overall shape (rectangular versus oval) and the specific compatible plate designs.

The reference device K110176 is for support of substantial equivalence of the subject device Insert for Cortical Screw Fixation. The 4 mm Locking Insert (K110176) and the subject device Insert for Cortical Screw Fixation have similar design features. The differences between the devices include the specific compatible plate designs, the use with locking (K110176) or non-locking cortical screws (subject device),

and the materials used for manufacturing (K110176 is manufactured from stainless steel, versus the subject device is manufactured from titanium alloy).

The plates and plate inserts from the subject device and the reference device K191848 are manufactured from the identical titanium alloy material conforming to ASTM F136. 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 previously cleared Medartis device components, including plates in K191848 and instruments and trays in K181425. Therefore, the subject device is substantially equivalent to the reference devices K191848 and K181425 regarding biocompatibility.

The subject device components and the Medartis device components cleared in K181425 are packaged using the same materials and are to be sterilized by the same methods.

Any minor differences in the technological characteristics among the subject device, the primary predicate device, the other predicate devices, and the reference devices do not impact safety or effectiveness.

The differences among the plates from the subject device, the primary predicate device, the other predicate devices, and the reference devices are 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 and screws from the primary predicate K111540 and the other predicate devices K073186 and K101536 are manufactured from a different titanium alloy (Ti-6Al-7Nb) material compared to the subject device material (Ti-6Al-4V). Similarly, the 4 mm Locking Insert from K110176 is manufactured from a different material (stainless steel). These slight differences among the subject device and the predicate and reference devices do not impact safety or effectiveness.

Mechanical performance of the subject device included comparative dynamic (fatigue) testing of worst-case, simulated clavicle fracture constructs. For three groups of the subject device plates (Superior Lateral Plates, Superior Midshaft and Lateral Shaft Plates, and Anterior Plates), the mechanically weakest subject device plate was selected for mechanical testing, and compared to a predicate device plate tested under the same conditions. Predicate device plates were selected based on the intended use (placement location on the clavicle for fixation of the specific fracture), the use of locking screws (as with the subject device plates), similar material, and similar dimensions. Based on the results of the testing, the performance of the subject device was judged to be substantially equivalent to the primary predicate K111540 and the other predicate devices K073186 and K101536. Static testing demonstrated that the tensile strength of suture-suture insert-plate constructs was significantly greater than the tensile strength of suture-simulated clavicle bone constructs.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and encompass a similar range of physical dimensions appropriate to the anatomy. The data included in this submission demonstrate substantial equivalence to the primary predicate device, the other predicate devices, and the reference devices listed above.

Substantial Equivalence – Indications for Use Statements

	Indications for Use Statement
Subject Device	
K192984 APTUS® Clavicle System Medartis AG	APTUS® Clavicle System is indicated for treatment of fractures, osteotomies, malunions and non-unions of the clavicle.
Primary Predicate Device	
K111540 Synthes 3.5 mm LCP Clavicle Plate System Synthes (USA)	The Synthes 3.5mm LCP Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.
Other Predicate Devices	
K073186 Synthes 3.5 mm LCP Clavicle Plate System Synthes (USA)	Synthes 3.5 mm LCP Clavicle Plate System is intended for fixation of fractures, malunions, non-unions. and osteotomies of the clavicle.
K101536 2.7/3.5 mm VA-LCP Anterior Clavicle Plate System Synthes (USA)	The Synthes 2.7 mm/ 3.5 mm VA-LCP Anterior Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.
K112111 Acu-Sinch Repair System Acumed LLC	The Acu-Sinch Repair System is intended to be used in conjunction with a clavicle plate of the Congruent Bone Plate System to provide fixation during the healing of clavicle fractures. The Acu-Sinch Repair System also may be used as a stand-alone system for treatment of acromioclavicular and/or coracoclavicular ligament disruption. The Acumed Suture Anchor is intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures: • Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction • Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair • Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Iliotibial Band Tenodesis • Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction • Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction Acumed's Locking Clavicle Plating System is designed to provide fixation during fractures, fusions, or osteotomies of the clavicle.
Reference Devices	
K110176 AxSOS® Locked Plating System Line Extension of 4 mm Locking Inserts Howmedica Osteonics Corp.	The AxSOS Locked Plating System in the Stryker Locked Plating System are intended for use in long bone fracture fixation. The AxSOS Locked Plating System is indicated for fixation of long bone fractures including fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia, and the distal femur.
K191848 APTUS® Wrist 2.5 System Medartis AG	APTUS® Wrist Spanning Plates 2.5 are intended for use in forearm fractures.
K181425 APTUS® Proximal Humerus System Medartis AG	APTUS® Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus. The 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.

Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate/Other Predicate Devices	Other Predicate Device	Reference Device	Reference Device	Reference Device
	K193984 APTUS® Clavicle System	K111540 (Primary Predicate Device) Synthes 3.5 mm LCP Clavicle Plate System K073186 (Other Predicate Device) Synthes 3.5 mm LCP Clavicle Plate System K101536 (Other Predicate Device) 2.7/3.5 mm VA-LCP Anterior Clavicle Plate System	K112111 Acu-Sinch Repair System	K110176 AxSOS® Locked Plating System Line Extension of 4 mm Locking Inserts	K191848 APTUS® Wrist 2.5 System	K181425 APTUS® Proximal Humerus System
	Medartis AG	Synthes USA	Acumed LLC	Howmedica Osteonics Corp.	Medartis AG	Medartis AG
Product Code	HRS	HRS (K111540; K073186) HRS, HWC (K101536)	HTN, HRS, HWC, MBI	HRS, HWC	HRS, HWC	HRS, HTY, HWC
Intended Use	Internal fixation of the upper extremity	Internal fixation of the upper extremity	Internal fixation of the upper extremity	Internal fixation of the upper and lower extremities	Internal fixation of the upper extremity	Internal fixation of the upper extremity
Reason for Predicate/Reference Device	Not applicable	Plate designs; Plates used in comparison mechanical testing	Acu-Sinch plate insert device design	Locking plate insert device design	Reference device for plate and plate insert material, Ti-6Al-4V alloy, ASTM F136	Reference device for device-specific template material (Unalloyed titanium, ASTM F67), and device-specific instruments and trays materials (stainless steel; PEEK; PPSU)
Plates			Plates described below are compatible with the Acu-Sinch insert device	Plates described below are compatible with the locking plate insert device		
Plate Designs	Anatomic plate designs Multiple designs and sizes Designs for superior and anterior surgical placement Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs Multiple sizes Multiple designs Designs for superior and anterior surgical placement Screw holes accommodate locking and non-locking (cortex) screws	Anatomic plate designs Multiple sizes Multiple designs Designs for superior and anterior surgical placement Screw holes accommodate locking and non-locking (cortex) screws Plate designs accommodate Acu-Sinch insert	Anatomic plate designs Multiple sizes Multiple designs Designs for superior and anterior surgical placement Screw holes accommodate locking and non-locking (cortex) screws Plate designs accommodate locking insert	Straight and anatomic plate designs (wrist) Two sizes (lengths) Designs for dorsal surgical placement Screw holes accommodate non-locking (cortex) and locking screws	Anatomic plate designs (proximal humerus) Multiple sizes; 3, 5, and 7 shaft screw hole plates; Specific plates for right and left proximal humerus; Screw holes accommodate conventional and locking screws; Locking blades
	Superior Midshaft Plates Superior Lateral Shaft Plates Superior Lateral Plates Anterior Midshaft Plates Anterior Lateral Plates	LCP Superior Clavicle Plates LCP Superior Anterior Clavicle Plates VA-LCP Anterior Clavicle Plates	Superior Midshaft Plates (low profile, narrow profile) Anterior Medial Plates Anterior Lateral Plates Superior Distal Plates	Proximal Humeral Plates Proximal Lateral Tibial Plates Distal Lateral Femoral Plates Distal Medial Tibial Plates Distal Anterolateral Tibial Plates		
Plate Features and Overall Dimensions (approximate)	Superior Midshaft Clavicle Plate Screw holes: 6, 8, 10, 12 Plate length: 83–141 mm Plate thickness 3.4 mm	LCP Superior Clavicle Plate 3.5 Screw holes: 6, 7, 8 Plate length: 94–123 mm Plate thickness: not available	Locking Clavicle Plate Screw holes: 6, 8, 10 Plate length: not available Plate thickness: not available	Not applicable (plates are not for the clavicle)	Not applicable (plates are not for the clavicle)	Not applicable (plates are not for the clavicle)
	Superior Lateral Shaft Clavicle Plate Screw holes: 11 Plate length: 94 mm Plate thickness 3.4 mm, tapering laterally	LCP Superior Clavicle Plate 2.7/3.5 with Lateral Extension Screw holes: 6, 7, 8 Plate length: 110–136 mm Plate thickness: not available	Locking Clavicle J-Plate Screw holes: 8, 9 Plate length: not available Plate thickness: not available			
	Superior Lateral Clavicle Plate Screw holes: 12, 14 Plate length: 78–100 mm Plate thickness 3.4 mm, tapering laterally	LCP Anterior Clavicle Plate 3.5 Screw holes: 6, 7, 8 Plate length: 79–102 mm Plate thickness: not available	Low-profile Superior Midshaft Clavicle Plate Screw holes: 8, 10 Plate length: not available Plate thickness: not available			
	Anterior Midshaft Clavicle Plate Screw holes: 6, 8, 10 Plate length: 82–118 mm Plate thickness 3.4 mm	VA-LCP Anterior Clavicle Plate 2.7/3.5 Screw holes: 7, 9, 10, 11, 12 Plate length: 77–124 mm Plate thickness 3.4 mm	Narrow-profile Superior Midshaft Clavicle Plate Screw holes: 6, 8 Plate length: not available Plate thickness: not available			
	Anterior Lateral Clavicle Plate Screw holes: 6 Plate length: 80 mm Plate thickness 3.4 mm	LCP Superior Anterior Clavicle Plate Screw holes: 3, 4, 5 Plate length: 94–120 mm Plate thickness 3.4 mm	Superior Distal Clavicle Plate Screw holes: 8, 9, 12, 13, 16 Plate length: not available Plate thickness: not available			
		LCP Superior Anterior Clavicle Plate 2.7/3.5 with Lateral Extension Screw holes: 3, 4, 5, 6, 7, 8 Plate length: 69–135 mm Plate thickness 3.4 mm	Anterior Medial Clavicle Plate Screw holes: 6, 8, 10 Plate length: not available Plate thickness: not available			

Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate/Other Predicate Devices	Other Predicate Device	Reference Device	Reference Device	Reference Device
	K193984 APTUS® Clavicle System	K111540 (Primary Predicate Device) Synthes 3.5 mm LCP Clavicle Plate System K073186 (Other Predicate Device) Synthes 3.5 mm LCP Clavicle Plate System K101536 (Other Predicate Device) 2.7/3.5 mm VA-LCP Anterior Clavicle Plate System	K112111 Acu-Sinch Repair System	K110176 AxSOS® Locked Plating System Line Extension of 4 mm Locking Inserts	K191848 APTUS® Wrist 2.5 System	K181425 APTUS® Proximal Humerus System
	Medartis AG	Synthes USA	Acumed LLC	Howmedica Osteonics Corp.	Medartis AG	Medartis AG
			Anterior Lateral Clavicle Plate Screw holes: 6, 8 Plate length: not available Plate thickness: not available			
Plate Materials	Ti-6Al-4V alloy, ASTM F136	Ti-6Al-7Nb alloy	Unalloyed titanium, ASTM F67 Ti-6Al-4V alloy, ASTM F136	Stainless steel, ASTM F138, ASTM F139	Ti-6Al-4V alloy, ASTM F136	Unalloyed titanium, ASTM F67
Plate Inserts						
Insert Designs	Insert for Suture Fixation Clavicle Thickness: 4 mm Length: 7.5 mm		Acu-Sinch insert device Suture retainer (suture button) Dimensional information not available			
	Insert for Cortical Screw Fixation Clavicle Thickness: 4 mm Length: 8.5 mm			4 mm Locking Insert Dimensional information not available		
Insert Materials	Ti-6Al-4V alloy, ASTM F136		Unalloyed titanium, ASTM F67 Ti-6Al-4V alloy, ASTM F136	Stainless steel, ASTM F138, ASTM F139		
Compatible Screws						
Screw Design	*Previously cleared Medartis APTUS Screws (K091479, 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*	*Compatible screws:* *Locking screws* *Cortical screws (non-locking)*	*Compatible screws:* *Locking screws* *Cortical screws (non-locking)* *Cancellous screws*	*Compatible screw information from catalog, not in K110167* *Locking screws* *Cortical screws* *Cancellous screws*	*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*	Locking screws: cortical thread form, double thread, self-tapping, fully threaded Non-locking screws: cortical thread form, single thread, self-tapping, fully threaded
Screw Diameters	*Previously cleared:* *2.8 mm (locking and non-locking)*	*Locking screws: 2.7 mm, 3.5 mm* *Cortical screws: 2.4 mm, 3.5 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*	*Compatible screw information from catalog, not in K110167* *Locking screws: 4.0 mm* *Cortical screws: 3.5 mm* *Cancellous screws: 4.0 mm*	*Previously cleared:* *2.5 mm (locking and non-locking)*	3.5 mm
Screw Lengths	*Previously cleared:* *8 mm to 36 mm (non-locking)* *8 mm to 36 mm (locking)*	*Locking screws* *14-32 mm (2.7 mm diameter)* *12–30 mm (3.5 mm diameter)* *Cortical screws* *14–30 mm (2.4 mm diameter)* *12–30 mm (3.5 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)*	*Compatible screw information from catalog, not in K110167* *Locking screws: 14-95 mm* *Cortical screws: 14-95 mm* *Cancellous screws:14-95 mm*	*Previously cleared:* *8 mm to 24 mm (non-locking)* *8 mm to 34 mm (locking)*	Locking and non-locking: 16 mm to 60 mm
Screw Materials	*Previously cleared:* *Ti-6Al-4V alloy, ASTM F136*	*Compatible screws:* *Ti-6Al-7Nb alloy*	*Compatible screws:* *Unalloyed titanium, ASTM F67* *Ti-6Al-4V alloy, ASTM F136*	*Compatible screws:* *Stainless steel, ASTM F138, ASTM F139*	*Previously cleared:* *Ti-6Al-4V alloy, ASTM F136*	Ti-6Al-4V alloy, ASTM F136
How Provided						
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	Provided non-sterile	Provided sterile	Provided non-sterile
Sterilization	End user to sterilize by moist heat	End user to sterilize by moist heat	End user to sterilize by moist heat	End user to sterilize by moist heat	X-ray beam irradiation	End user to sterilize by moist heat
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