March 16, 2026

Medartis AG
Salvatore Risoli
Group Manager Regulatory PLM
Hochbergerstrasse 60e
Basel, 4057
Switzerland

Re: K253916
Trade/Device Name: APTUS Shoulder Proximal Humerus System, PentaLock 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
Dated: October 23, 2025
Received: December 8, 2025

Dear Salvatore Risoli:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253916

Please provide the device trade name(s).

APTUS Shoulder Proximal Humerus System, PentaLock 3.5

Please provide your Indications for Use below.

APTUS Shoulder Proximal Humerus System, PentaLock 3.5, is indicated for fractures, osteotomies and non-unions of the proximal humerus.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253916

510(k) Summary

Prepared on: 2025-12-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medartis AG
Applicant Address	Hochbergerstrasse 60E Basel 4057 Switzerland
Applicant Contact Telephone	+41616333771
Applicant Contact	Salvatore Risoli
Applicant Contact Email	salvatore.risoli@medartis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	APTUS Shoulder Proximal Humerus System, PentaLock 3.5
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K120108	APTUS PROXIMAL HUMERUS SYSTEM	HRS
K181425	APTUS® Proximal Humerus System	HRS,HWC,HTY
K243610	APTUS Hand System	HRS,HWC

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this submission is to obtain marketing clearance for an additional device design within the Medartis APTUS Shoulder Proximal Humerus System portfolio.
The subject device "APTUS Shoulder Proximal Humerus System, PentaLock 3.5" comprises plates, spiral blades, PentaLock locking screws, and cortical screws, available in both sterile and non-sterile configurations.
The plates are offered in five designs for both the left and right proximal humerus and are intended for use with PentaLock locking screws and cortical screws.
The spiral blades are available in left and right versions with angulations of 50° and 40°, respectively. Each spiral blade is secured to the plate using two screws.
All screws feature self-tapping cortical thread forms with a thread diameter of 3.5 mm and are provided in various overall lengths ranging from 16 mm to 60 mm. PentaLock screws include a locking threaded head.
The system includes device-specific Class II instruments as well as general instruments.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

APTUS Shoulder Proximal Humerus System, PentaLock 3.5, is indicated for fractures, osteotomies and non-unions of the proximal humerus.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The APTUS Shoulder Proximal Humerus System, PentaLock 3.5 has the same intended use and Indications for Use as the primary predicate device K120108 APTUS Proximal Humerus System and the additional predicate cleared under K181425 APTUS® Proximal Humerus System.

Technological Comparison 21 CFR 807.92(a)(6)

APTUS Shoulder Proximal Humerus System, PentaLock 3.5 is substantially equivalent to the primary predicate device K120108 APTUS Proximal Humerus System and the additional predicate devices cleared under K181425 APTUS® Proximal Humerus System and K243610 APTUS Hand System. They share the same or similar technological characteristics, materials and dimensions.
Any differences do not raise new questions regarding safety or effectiveness. Overall, the APTUS Shoulder Proximal Humerus System, PentaLock 3.5 has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates similar materials.

The trilock design on the predicate devices has been modified to a Pentalock design. The reference devices cleared under K243610 support the sterility validation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing of the APTUS Shoulder Proximal Humerus System with PentaLock 3.5 included construct testing under worst-case test set-up to demonstrate substantial equivalence, as referenced in K120108.
Additionally Medartis APTUS PentaLock 3.5 locking and non-locking screws were tested according to ASTM F543. The results were compared against the acceptance criteria outlined in the FDA Guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway".

Clinical Data and conclusions were not needed for this device.

Their performance has been evaluated against previously cleared predicate devices, which met all acceptance criteria.
The new devices fall within the performance and design characteristics of the previously cleared devices, thereby demonstrating the safety and effectiveness of the product line.