June 5, 2026

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

Re: K260761
Trade/Device Name: APTUS Clavicle System 2.8
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: March 9, 2026
Received: March 9, 2026

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.	K260761

Please provide the device trade name(s).

APTUS Clavicle System 2.8

Please provide your Indications for Use below.

Implants from the APTUS Clavicle System are indicated for the treatment of fractures and osteotomies of the clavicle, and for dislocations of the acromioclavicular joint.

Clavicle plates
- fractures, osteotomies, malunions and non-unions of the clavicle

Clavicle Hook Plates
- fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

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

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

510(k) #:

510(k) Summary

Prepared on: 2026-06-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medartis AG
Applicant Address	Hochbergerstrasse 60E Basel 4057 Switzerland
Applicant Contact Telephone	+41797728067
Applicant Contact	Mr. Salvatore Risoli
Applicant Contact Email	Salvatore.Risoli@medartis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	APTUS Clavicle System 2.8
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192984	APTUS® Clavicle System	HRS
K111540	SYNTHES 3.5MM LCP CLAVICLE PLATE SYSTEM	HRS
K243610	APTUS Hand System; APTUS Elbow Dorsal Olecranon	HRS
K061753	Synthes (USA) Clavicle Hook Plate	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this submission is to obtain marketing clearance for an additional device design to expand the range of the Medartis APTUS Clavicle System, previously cleared under K192984.
The subject device APTUS Clavicle System 2.8 consists of Clavicle Plates and Hook Plates, available in both sterile and non-sterile configurations.
The clavicle plates are offered in nine designs for both, the left and right clavicle, and are intended for use with TriLock locking screws and cortical screws.
The hook plates are offered in 18 designs for both, the left and right clavicle and are intended for use with TriLock locking screws and cortical screws.
The system includes device-specific Class II instruments as well as general instruments.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Implants from the APTUS Clavicle System are indicated for the treatment of fractures and osteotomies of the clavicle, and for dislocations of the acromioclavicular joint.

Clavicle plates
- fractures, osteotomies, malunions and non-unions of the clavicle

Clavicle Hook Plates
- fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint

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

The APTUS Clavicle System 2.8 has the same intended use and Indications for Use as the primary predicate device K192984 APTUS® Clavicle System and the additional predicate cleared under K111540 SYNTHES 3.5MM LCP CLAVICLE PLATE SYSTEM and K061753 Device Synthes (USA) Clavicle Hook Plate.

Technological Comparison 21 CFR 807.92(a)(6)

APTUS Clavicle System 2.8 is substantially equivalent to the primary predicate device K192984 APTUS® Clavicle System and the additional predicate devices cleared under K111540 SYNTHES 3.5MM LCP CLAVICLE PLATE SYSTEM, K061753 Device Synthes (USA) Clavicle Hook Plate and APTUS Hand System K243610.
They share the same or similar technological characteristics, materials and dimensions.
Any differences do not raise new questions regarding safety or effectiveness. Overall, APTUS Clavicle System 2.8 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.

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

Bench testing of the APTUS Clavicle System 2.8 included construct testing under worst-case test set-up to demonstrate substantial equivalence.
The subject device APTUS Superior Lateral Plates and APTUS Superior Lateral Shaft Plates does not constitute a new worst case within the predicate device APTUS Clavicle System, previously cleared in K192984. Therefore, the already existing performance data from the predicate device is sufficient to demonstrate safety and performance.
The subject device APTUS Superior-Anterior Clavicle Plate included construct testing under worst-case test set-up to demonstrate substantial equivalence with predicate device LCP Superior Clavicle Plate 3.5 (DePuy Synthes), previously cleared in K111540.
The subject device APTUS Clavicle Hook Plate included construct testing under worst-case test set-up to demonstrate substantial equivalence with predicate device Clavicular Hook Plate 3.5 (DePuy Synthes), previously cleared in K061753.

Endotoxin testing is performed using the Limulus Amebocyte Lysate (LAL) assay in accordance with ANSI/AAMI ST72, USP <85>, and ISO 11737.

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 product line is substantially equivalent.