March 7, 2025

Medartis AG
Zurbuchen-De Santis Claudia
Head Global Regulatory Affairs & PLM
Hochbergerstrasse 60E
Basel, BS 4057
Switzerland

Re: K243610
Trade/Device Name: APTUS Hand System; APTUS Elbow Dorsal Olecranon
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: February 5, 2025
Received: February 5, 2025

Dear Zurbuchen-De Santis Claudia:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243610

Device Name

APTUS Hand System;
APTUS Elbow Dorsal Olecranon

Indications for Use *(Describe)*

APTUS Hand
Fractures, osteotomies and arthrodesis of the bones of the hand

- Hand System
  - fractures of the distal, middle and proximal phalanges
  - fractures of the metacarpals
  - osteotomies of the hand
  - arthrodeses in the hand

- Scaphoid plates
  - fractures and non-unions of the scaphoid

The APTUS Elbow Dorsal Olecranon Plates are indicated for fractures and osteotomies, in particular for the ulna.

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.

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510(k) #: K243610

510(k) Summary

Prepared on: 2025-03-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medartis AG
Applicant Address	Hochbergerstrasse 60E Basel BS 4057 Switzerland
Applicant Contact Telephone	+41798835288
Applicant Contact	Ms. Claudia Zurbuchen-De Santis
Applicant Contact Email	claudia.desantis@medartis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	APTUS Hand System; APTUS Elbow Dorsal Olecranon
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
K051567	APTUS TITANIUM OSTEOSYNTHESIS SYSTEM	HRS
K240613	APTUS Elbow Dorsal Olecranon Plates	HRS
K232144	Sterile Products of the APTUS System	HRS
K102537	APTUS 1.5 TRILOCK	HRS
K234062	APTUS Hand Scaphoid Plates	HRS

Device Description Summary

21 CFR 807.92(a)(4)

APTUS Hand System
The purpose of this submission is to obtain marketing clearance for an additional device design to expand the range of the Medartis APTUS Hand System, previously cleared under K102537, K051567, K232144 and K234062.

The subject device includes the APTUS Hand System , which is used for fractures, osteotomies and arthrodesis of the bones of the hand. APTUS Hand plates are offered in two main system sizes, 1.2/1.5 and 2.0/2.3, depending on the screw size. The subject device plates are to be used with Medartis APTUS TriLock locking screws, cortical screws and SpeedTip screws.
- Non-locking plates 1.2/1.5 use cortical screw sizes of either 1.2 or 1.5 mm, and SpeedTip screw size of 1.5mm
- TriLock locking plates 1.2/1.5 use locking screws sizes of either 1.2 or 1.5 mm, but also accepts cortical screw sizes of 1.2 or 1.5mm as well as SpeedTip screw size of 1.5mm
- TriLock locking plates 2.0/2.3 use locking screws size of 2.0 mm, but also accepts cortical screw sizes of 2.0 or 2.3 mm

The APTUS Hand plates are anatomically pre-contoured with respect to the anatomy of the specific bone they are designed for. Most plates may be additionally cut and bent intraoperatively for a wide range of applications.
The subject device screws consist of non-sterile and sterile TriLock Screws (locking)and SpeedTip Screws (non-locking).
TriLock Screw heads have spherical three point wedge locking design to create a friction-lock connection through radial bracing of the screw head in the plate, thereby creating uniform distribution of stresses over the screw head and plate.
The SpeedTip Screws feature a self-cutting screw tip for insertion without prior drilling.

The subject device plates are compatible with washers, screws and k-wires previously cleared K102537 and K051567 (for washers and screws) and K092038 (for k-wires).
Plate designs are available either non-sterile or sterile. Plates provided non-sterile are intended to be sterilized by the end user before use.
The 510(k) of the subject devices K051567 and K102537 APTUS Hand Group and K234062 APTUS Hand Scaphoid will be grouped in the APTUS Hand System. As a result, the indication will be updated for better clarity. This change does not affect the design, materials, or functionality of the devices.

APTUS Elbow Dorsal Olecranon Plates
The purpose of this 510(k) submission is to obtain marketing clearance for the Sterile Products of the APTUS Elbow Dorsal Olecranon Plates to expand the range of Medartis APTUS fixation devices provided to the end user in a sterile condition. The non-sterile devices were previously cleared under K240613.
The sterilization process proposed for the Sterile Products of the APTUS System has also already been cleared under K232144, Sterile Products of the APTUS System, the reference device for this submission.

The Indication for Use, the Design and the Material are the same as in the previously cleared predicate device K240613 APTUS Elbow Dorsal Olecranon Plates.

Sterile Products of the APTUS Elbow Dorsal Olecranon screws are made of titanium alloy conforming to ASTM F136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).
Sterile products of the APTUS Elbow Dorsal Olecranon K-wires are made of stainless steel conforming to ASTM F138 Standard Specification for Wrought 18 Chromium -14 Nickel-2.5 Molybdenum Stainless Steel Wire for Surgical Implants (UNS S31673).

Sterile products of the APTUS Elbow Dorsal Olecranon washers are made of unalloyed titanium, Grade 4, conforming to ASTM F67.

In summary, the Sterile Products of the APTUS Elbow Dorsal Olecranon has the following similarities to the predicate device previously cleared in K240613:
• has the same intended use and indications for use,
• uses the same operating principle,
• incorporates the same basic design,
• incorporates the same materials

In summary, the Sterile Products of the APTUS Elbow Dorsal Olecranon has the following similarities to the predicate device previously cleared in K240613 and K232144:
• has modified packaging so the device can be provided to the end user in a sterile condition.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

APTUS Hand
Fractures, osteotomies and arthrodesis of the bones of the hand

- Hand System
  - fractures of the distal, middle and proximal phalanges
  - fractures of the metacarpals
  - osteotomies of the hand
  - arthrodeses in the hand

- Scaphoid plates
  - fractures and non-unions of the scaphoid

The APTUS Elbow Dorsal Olecranon Plates are indicated for fractures and osteotomies, in particular for the ulna.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use Statements (IFUS) for the APTUS Hand System include language for fractures, osteotomies and arthrodesis, which is covered by the Indications for Use Statements (IFUS) for the primary predicate device K051567 and K234062.

The APTUS Elbow Dorsal Olecranon has the same intended use and Indications for Use as the predicate cleared under K240613.

The subject device is part of the APTUS Hand System and APTUS Elbow system, which in turn is part of the APTUS fixation system. The intended use of the APTUS fixation system includes fractures, osteotomies and arthrodesis of the hand, forearm, shoulder and foot. This covers the intended use of the primary predicate device, which includes the fixation of fractures of the hand and ulna.

Technological Comparison

21 CFR 807.92(a)(6)

The primary predicate device K051567 and the additional predicate devices K102537 is in support of substantial equivalence in terms of same technological characteristics, similar design characteristics (including screw holes to accommodate locking and non-locking screws), similar principle of operation and similar material for the APTUS Hand.
The predicate device K240613 is in support of substantial equivalence in terms of same technological characteristics, similar design characteristics, similar principle of operation and similar material for the APTUS Elbow Dorsal Olecranon.

The reference devices cleared under K232144 are in support of substantial equivalence in terms of sterility.

All subject device final finished components are manufactured using identical material and same manufacturing steps as used for the primary predicate device K051567 and the additional predicate devices K102537 and K240613 and therefore, are substantially equivalent to these previously-cleared devices regarding biocompatibility.

The primary predicate device K051567 and the additional predicate devices K102537 and K240613 is in support of substantial equivalence in terms of same moist heat sterilization process for subject devices provided non-sterile to the end user and are packaged using the same material.
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 additional predicate K232144.

In summary, the subject devices have the following similarities to the predicate devices:
- has the same intended use and indications for use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials,
- Incorporates the same moist heat sterilization
- has modified packaging so the device can be provided to the end user in a sterile condition.

Conclusion
- The APTUS Hand System and the APTUS Elbow Olecranon possess similar indications for use and technological characteristics as the predicate devices. The device modifications to not raise any new questions of safety and effectiveness. Therefore, the subject devices are substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non clinical evaluation of the APTUS Hand System plates and screws and the APTUS Elbow Olecranon devices demonstrated that the performance of the subject devices is substantially equivalent to the predicate devices in terms of safety and efficacy.

The performance testing of the APTUS Hand Plate System demonstrates the safety and performance of the screws by evaluating torsional properties, driving torque, axial pullout, and self-tapping performance with full insertion in accordance with ASTM F543 as well as the performance of the plates in combination with the screws in a comparison between the worst case devices from the subject and predicate devices. The testing demonstrated that the new APTUS Hand System plates do not represent a new worst case when compared to predicate devices.

No new testing of the APTUS Elbow Dorsal Olecranon was conducted as there were no changes to the design, materials, or manufacturing processes in the current submission. The identical devices were cleared in K240692.
The sterilization process used for the APTUS Hand System and the APTUS Elbow dorsal Olecranon was cleared in K232144.

Clinical data was not required to establish substantial equivalence of the subject devices to the predicate devices.