June 20, 2024

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

Re: K240613
Trade/Device Name: APTUS Elbow Dorsal Olecranon Plates
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: March 5, 2024
Received: May 21, 2024

Dear Claudia De Santis:

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.

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

Digitally signed by Thomas Mcnamara -S
Date: 2024.06.20 16:21:01 -04'00'

For
Shumaya Ali, M.P.H.
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)*

K240613

Device Name

APTUS Elbow Dorsal Olecranon Plates

Indications for Use *(Describe)*

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) #: K240613

510(k) Summary

Prepared on: 2024-06-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medartis AG
Applicant Address	Hochbergerstrasse 60E Basel BS 4057 Switzerland
Applicant Contact Telephone	+41 798835288
Applicant Contact	Mrs. Claudia De Santis
Applicant Contact Email	claudia.desantis@medartis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	APTUS Elbow Dorsal Olecranon Plates
Common Name	Plate, Fixation, Bone; Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories (Primary), Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3030 (Primary), 888.3040
Product Code(s)	HRS (Primary), HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K120070	SYNTHES VARIABLE ANGLE LCP ELBOW SYSTEM	HRS
K193633	APTUS Ankle Trauma System 2.8/3.5	HRS
K193639	APTUS Foot System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this submission is to obtain marketing clearance for new APTUS Elbow Dorsal Olecranon Plates.

The subject device APTUS Elbow Dorsal Olecranon Plates are available in three (3) designs: Standard, Medium and Extended. The designs differ in the shape of the proximal ends of the plate. The Standard Plates are available in 6 lengths; The Medium Plates are available in 2 lenghts and the Extended Plates are available in 3 lenghts, each for left and right. All plates have anatomical designs that are appropriate for the olecranon. The subject device plates are compatible with screws and k-wires previously cleared in K051567, K091479, K103332, K112560, K232144 (for screws) and K092038 (for k-wires).

The subject device plates are manufactured from titanium alloy, conforming to ASTM F136. All plates are provided sterile and selected plates are provided non-sterile aswell.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 primary predicate device K120070 include language for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna. The Indications for Use Statements (IFUS) for the subject device include language for fractures and osteotomies of the ulna, which is covered by the Indications for Use Statements (IFUS) for the primary predicate device K120070.

The subject device is part of the 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 distal humerus, olecranon and ulna.

Technological Comparison

21 CFR 807.92(a)(6)

The primary predicate device K120070 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 plate material.
The additional predicate devices K193633 and K193554 are in support of substantial equivalence in terms of same design characteristics regarding screw holes to accommodate Trilock locking and non-locking (cortical) screws.

All subject device final finished components (plates) are manufactured using identical material and same manufacturing steps as used for the additional predicate devices K193633 and K193639, and therefore, are substantially equivalent to these previously-cleared devices regarding biocompatibility.

The additional predicate K193633 is in support of substantial equivalence in terms of same 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 K193633.
Clinical data were not provided in this submission.

The subject device plates are compatible with Medartis screws previously cleared in K051567, K091479, K103332, K112560 and K232144.
The subject device plates also are compatible with Medartis K-Wires previously cleared in K092038.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The safety and performance of the plates were established by performing static testing according to ASTM F382 and comparing the results to the minimum requirements pointed out in the relative FDA guidance: Guidance for Industry and Food and Drug Administration Staff, Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway (2022).
Clinical data were not provided in this submission.

The mechanical test results show that the bending strength and bending structural stiffness of the Dorsal Olecranon Medartis APTUS Elbow Plates are higher than the acceptance values indicated in the relative FDA guidance (Guidance for Industry and Food and Drug Administration Staff, Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway (2022)).
Clinical data were not provided in this submission.

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device, the primary predicate, and the additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.