March 21, 2024

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

Re: K234062
Trade/Device Name: APTUS Hand Scaphoid 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
Dated: December 7, 2023
Received: December 22, 2023

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,

Shumaya Ali -S

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K234062

Device Name

APTUS Hand Scaphoid Plates

Indications for Use *(Describe)*

APTUS Hand Scaphoid Plates are indicated for fractures and non-unions of the scaphoid.

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) Summary

Prepared on: 2023-12-21

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 Hand Scaphoid Plates
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K102537	1.2/1.5 TriLock Plate 3/5 Hole T, t0.8	HRS
K223853	2.5 TriLock Distal Ulna Plates	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® Hand Plates, previously cleared under K102537.
The subject device APTUS Hand Scaphoid Plates is available in three designs - small, standard, large - all with 6 screw holes. All plates have anatomical designs that are appropriate for the scaphoid. The subject device plates are compatible with screws and k-wires previously cleared in K102537, K051567, K232144 (for srews), K092038, K202589 and K232144 (for k-wires).
The subject device plates are manufactured from unalloyed titanium conforming to ASTM F67, and are provided non-sterile and sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

APTUS Hand Scaphoid Plates are indicated for fractures and non-unions of the scaphoid.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use Statements (IFUS) for the primary predicate device K102537 include language for fractures in hand, in particular transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft factures, comminuted fractures, dislocation fractures, avulsion fractures. The Indications for Use Statements (IFUS) for the subject device include language for fractures and non-unions of the scaphoid, which is covered in the Indications for Use Statements (IFUS) for the primary predicate device K102537. The intended use of the subject device and the primary predicate device is identical: The APTUS fixation systems are used for fractures, osteotomies and arthrodesis of the hand, forearm, shoulder and foot.

Technological Comparison 21 CFR 807.92(a)(6)

The primary predicate K102537 and the additional predicate K223853 are in support of substantial equivalence in terms of same technological characteristics and similar design characteristics (including screw holes to accommodate locking and non-locking screws), same principle of operation, same plate material, the same moist heat sterilization process for devices provided non-sterile to the end user and are packaged using the same material. K102537 is also for support of substantial equivalence in terms of comparative mechanical testing (dynamic testing).

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 K223853.
Clinical data were not provided in this submission.

The subject device plates are compatible with Medartis screws previously cleared in K102537, K232144 (TriLock) and K051567, K232144 (Cortical). The subject device plates also are compatible with Medartis K-Wires previously cleared in K092038, K202589 and K232144.

All subject device final finished components (plates) are manufactured using identical materials and same manufacturing steps as used for the primary predicate K102537, and therefore, are substantially equivalent to this previously-cleared device regarding biocompatibility.

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

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence
included: Mechanical fatigue and static testing. Based on the results of the testing, the performance of the subject device was judged to be substantially equivalent to the primary predicate device, previously cleared with K102537. Clinical data were not provided in this submission.

Not Applicable

The mechanical test results show that the subject device performs better than the predicate device, when subjected to worst case static and fatigue testing. Clinical data were not provided in this submission.