April 19, 2024

Medartis AG
Claudia Santis
Head of Regulatory Affairs
Hochbergerstrasse 60E
Basel, Basel-Stadt CH-4057
Switzerland

Re: K232105
Trade/Device Name: APTUS Foot System 2.8-3.5
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, PLF
Dated: March 13, 2024
Received: March 21, 2024

Dear Claudia 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,

Tejen D. Soni -S

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)*

K232105

Device Name

APTUS Foot System 2.8-3.5

Indications for Use *(Describe)*

The APTUS Foot System 2.8-3.5 is indicated for use in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.

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: 2024-04-10

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 Foot System 2.8-3.5
Common Name	Plate, Fixation, Bone (Primary); Screw, Fixation, Bone; Bone Wedge
Classification Name	Single/multiple component metallic bone fixation appliances and accessories (Primary); Smooth or threaded metallic bone fixation fastener
Regulation Number	21 CFR 888.3030 (Primary); 21 CFR 888.3040
Product Code(s)	HRS (Primary); HWC; PLF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193639	APTUS® Foot 2.8 – 3.5 System	HRS
K223853	Medartis APTUS® Ulna Plates	HRS
K091479	APTUS FOOT SYSTEM	HRS
K052614	LOW PROFILE PLATE AND SCREW SYSTEM	HRS
K150520	DARCO Locking Bone Plate System	HRS
K103332	APTUS ULNA PLATES	HRS
K193633	APTUS® Ankle Trauma System 2.8/3.5	HRS
K110908	APTUS FOOT 3.5 SYSTEM	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 Foot System 2.8-3.5 previously cleared under K193639.

The subject device Medartis APTUS Foot System 2.8-3.5 consisting of following plates and systems: 2.8 TriLock Plate Straight, 2.8 TriLock Plate Hole T Extended and 2.8 TriLock TMT-1 Medial Fusion Plates Large, APTUS Mid- and Hindfoot System 2.8/3.5 and Fusion System 3.5.

The APTUS Mid- and Hindfoot System 2.8/3.5 includes TriLock 2.8 C Plates, 2.8 TriLock Calcaneus LCL Plates, 3.5 TriLock Calcaneus LCL Plates and 3.5 TriLock Calcaneus Step Plates.
The subject device also includes sterile wedges that are used to support fixation of an opening wedge osteotomy. The wedges are stabilized by corresponding wedge screws that are placed through a plate.
The subject device wedges are provided in two size series.

The APTUS Fusion System 3.5 includes 3.5 TriLock Wing Plates, 3.5 TriLock Butterfly Plates, 3.5 TriLock TNC Fusion Plates, 3.5 TriLock NCM Fusion Plates, 3.5 TriLock TNCM Fusion Plates, 3.5 TriLock Talonavicular Fusion Plates. Furthermore, 3.5 TriLock Medial Column Fusion Plates, 3.5 TriLock Distal Medial Column Fusion Plates, 3.5 TriLock Proximal Column Fusion Plates.

The APTUS Fusion System 3.5 plates include screw holes designed to accommodate appropriately sized bone screws and K-wires presently marketed as part of the APTUS System.
The 2.8 TriLock Straight Plates are generic straight plates and used with 2.8 mm screws.
The 2.8 TriLock Plate Hole T Extended are generic T plates and used with 2.8 mm screws.
The 2.8 TriLock TMT-1 Medial Fusion Plates Large plates have anatomical designs that are appropriate for either the left or the right foot.

The subject device plates are manufactured from unalloyed titanium, Grade 4, conforming to ASTM F67 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNSR50250, UNS R50400, UNS R50550, UNS R50700).

The subject device sterile screws consist of sterile TriLock screws (locking), Cortical and Cancellous screws (non-locking).
The APTUS TriLock Screws, Cortical Screws and Cancellous Screws that are compatible with the subject device plate are manufactured from titanium alloy conforming to ASTM F136.
The APTUS K-Wires that are compatible with the subject device plates are manufactured from stainless steel conforming to ASTM F138 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).
The device-specific instruments (templates) are manufactured from unalloyed titanium, Grade 4, conforming to ASTM F67 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNSR50250, UNS R50400, UNS R50550, UNS R50700).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The APTUS Foot System 2.8-3.5 is indicated for use in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use Statements (IFUS) for the subject device and the primary predicate device K193639 include language for fractures, osteotomies and arthrodesis, in particular for the tarsals, metatarsals and phalanges. The IFUS for the subject device and the primary predicate device K193639 is identical.

Technological Comparison

21 CFR 807.92(a)(6)

The primary predicate device K193639 is in support of substantial equivalence for the subject device in terms of identical IFUs, similar plate designs; compatible screw and K-wire designs (use with locking and non-locking screws); identical plate materials and the same non-sterile packaging. The primary predicate device K193639 is also for support of substantial equivalence in terms of comparative mechanical testing.
The additional predicate device K223853 is in support of substantial equivalence for the subject device in terms of identical plate material, similar technological and design characteristics, including use with locking and non-locking screws and K-wires, same sterilization for devices provided nonsterile, same sterilization for devices provided sterile, the same packaging, and the same sterile barrier shelf life.
The additional predicate K223853 is also for support of substantial equivalence in terms of

comparative sterilization and shelf life.
The primary predicate device K193639 and the additional predicate devices K091479, K052614 and K150520 are in support of substantial equivalence for the subject device in terms similar plate designs, compatible screw and K-wire designs (use with locking and non-locking screws); identical plate materials and the same non-sterile packaging. The additional predicates are also for support of substantial equivalence in terms of comparative mechanical testing.
The screws from the subject device have the same technological characteristics, identical design characteristics, and identical material previously cleared in K193639, K091479, K103332 and K110908.
The additional predicate device K193633 is in support of substantial equivalence for the subject device in terms of identical screw material, similar technological and design characteristics, same sterilization for devices provided nonsterile, same sterilization for devices provided sterile, the same packaging, and the same sterile barrier shelf life. The additional predicate device K193633 is also for support of substantial equivalence in terms of comparative sterilization and shelf life.
The basis for the belief of Medartis AG that the subject device is substantially equivalent to the predicate devices is summarized in the Tables of Substantial Equivalence.
The primary predicate device K193639 is in support of substantial equivalence for the device specific (Class II) instruments and accessories in terms of same materials, same packaging, and same sterilization (moist heat by end user).
The subject device and the device specific (Class II) instruments and accessories are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the primary predicate device K193639 and the additional predicate devices K223853, K091479, K103332 K110908 and therefore, are substantially equivalent to these previously-cleared devices regarding biocompatibility.

CONCLUSION
Overall, the subject device has the following similarities to the predicate devices:
- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has the same packaging and is sterilized using the same materials and processes.

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

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

Fatigue testing was performed with the Plates of Mid- and Hindfoot System 2.8/3.5 and Fusion Plates according to ASTM F382-17 to demonstrate equivalence to the predicate devices listed in K193639, K091479, K052614 and K150520.
Foot Plates are covered by the worst case product cleared in K091479. Worst case plates were identified based on their out of plane bending moments of inertia.

Not Applicable

The mechanical test results show that the acceptance criteria were met.
Clinical data were not provided in this submission.