March 30, 2023

Medartis AG
Claudia De Santis
Sr. Regulatory Affairs Specialist
32 Wiggins Avenue
Beford, Massachusetts 01730

Re: K223853
Trade/Device Name: APTUS 2.5 TriLock Distal Ulna 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: November 10, 2022
Received: December 23, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jesse Muir -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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K223853

Device Name

APTUS 2.5 TriLock Distal Ulna Plates

Indications for Use *(Describe)*

APTUS Ulna 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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K223853

# 510(k) Summary

## Medartis AG
## APTUS 2.5 TriLock Distal Ulna Plates
## March 2, 2023

ADMINISTRATIVE INFORMATION

| | |
|---|---|
| Manufacturer Name | Medartis AG<br>Hochbergerstrasse 60E<br>CH-4057 Basel, Switzerland<br>Telephone: +41 61 633 34 34 |
| Official Contact | Claudia De Santis<br>Head Regulatory Affairs<br>Email: claudia.desantis@medartis.com<br>Telephone: +41 79 883 52 88 |
| Additional correspondent | Salvatore Risoli<br>Senior Regulatory Affairs Manager<br>Email: salvatore.risoli@medartis.com<br>Telephone: +41 61 633 37 72 |

DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Device Name | APTUS 2.5 TriLock Distal Ulna Plates |
| Common Name | Plate, Fixation, Bone |
| Regulation Number | 21 CFR 888.3030 |
| Regulation Name | Single/multiple component metallic bone fixation appliances and accessories |
| Regulatory Class | Class II |
| Product Codes | HRS |
| Classification Panel | Orthopedic |

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K103332, APTUS Ulna Plates, Medartis AG;

Additional Predicate Devices
K193633, APTUS® Ankle Trauma System 2.8/3.5, Medartis AG;
K193554, APTUS® Forearm, Medartis AG;
K192984, APTUS® Clavicle System, Meadrtis AG;
K192297, APTUS® Wrist Arthrodesis Plates, Medartis AG;
K142906, APTUS® Wrist 2.5 System, Medartis AG

INDICATIONS FOR USE STATEMENT
APTUS Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.

SUBJECT DEVICE DESCRIPTION
The purpose of this submission is to obtain marketing clearance for an additional device design to expand the range of the Medartis APTUS® Ulna Plates, previously cleared under K103332.
The subject device APTUS Distal Ulna Plates is available in four (4) designs with 10 or 12 screw holes. All plates have anatomical designs that are appropriate for either the left or the right ulna. The 10 and 12 hole plates have a length of 53 mm and 66 mm, respectively. The maximum thickness of the plates is 1.6 mm and the maximum width is 15 mm.
The subject device plates include screw holes designed to accommodate appropriately sized bone screws and K-wires presently marketed as part of the APTUS System. The subject device plates are compatible with screws and K-wires previously cleared in K051567 (TriLock), K103332 (cortical), and K092038 (K-wires).

The subject device plates are manufactured from unalloyed titanium, Grade 4, conforming to ASTM F67, and are provided non-sterile and sterile.

PERFORMANCE DATA
Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: Mechanical testing *Fatigue Bending Test* and *Static Bench Testing.* Based on the results of the testing, the performance of the subject device was judged to be substantially equivalent to the primary predicate K103332. Clinical data were not provided in this submission.

EQUIVALENCE TO MARKETED DEVICES
The primary predicate K103332 is in support of substantial equivalence for the subject device in terms of identical IFUs, similar design characteristics; compatible screw and K-wire designs (use with 2.5 locking and 2.5 non-locking screws); identical plate material, the same packaging and the same sterilization for devices provided non-sterile to the end user. K103332 is also for support of substantial equivalence in terms of comparative mechanical testing.

The additional predicate devices K193633 is in support of substantial equivalence for the subject device in terms of same plate material, same processing, similar technological and design characteristics, including use with locking and non-locking screws and K-wires, same sterilization for devices provided non-sterile, same sterilization for devices provided sterile, the same packaging, and the same sterile barrier shelf life.

The plates from the subject device and the primary predicate device K103332 have similar technological characteristics, have similar design characteristics, and include screw holes to accommodate 2.5 locking and 2.5 non-locking screws.
The subject device plates are compatible with Medartis screws previously cleared in K051567 and K103332, including 2.5 TriLock (locking) and 2.5 cortical (non-locking) screws. The subject device plates also are compatible with Medartis K-Wires previously cleared in K092038.

The additional predicate devices K193633, K193554 and K192984 are 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 K103332 and the additional predicate devices K193633, K193554, K192984, K192297 and K142906, 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 a similar plate design,
- incorporates the same materials, and
- has 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.