August 18, 2023

Medartis AG
% Chelsea Kozior
Regulatory Affairs Manager
Medartis Inc.
1195 Polk Drive
Warsaw, Indiana 46582

Re: K232144
Trade/Device Name: Sterile Products of the APTUS System
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: July 17, 2023
Received: July 19, 2023

Dear Chelsea Kozior:

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,

Shumaya Ali -S

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232144

Device Name
Sterile Products of the APTUS System

Indications for Use *(Describe)*

APTUS® Titanium Fixation System
The APTUS® Titanium Fixation System is indicated for use in hand and forearm fractures, osteotomies and arthrodeses.
APTUS® Hand group:
• Management of the fractures of the distal, middle and proximal phalanges and metacarpals
• Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft fractures, comminuted fractures, dislocation fractures, avulsion fractures
• DIP and PIP arthrodeses
APTUS® Radius 2.5 group:
• Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures
• Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions.

APTUS® 2.0/2.3 Four Corner Fusion Plate
The APTUS® 2.0/2.3 Four Corner Fusion Plate, an addition to the APTUS® Titanium Fixation System, is designed specifically for fusion of carpal bones including: hamate, capitate, lunate, triquetrum and is for use in patients suffering pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis. The fusion plate is used in conjunction with locking and non-locking screws that fix the plate to the carpal bones of the hand.

APTUS® K-Wire System
The APTUS® K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

APTUS® 1.5 TriLock
The APTUS® 1.5 TriLock is indicated for use in hand and forearm fractures, osteotomies and arthrodeses.
APTUS® Hand group:
• Management of the fractures of the distal, middle and proximal phalanges and metacarpals
• Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft fractures, comminuted fractures, dislocation fractures, avulsion fractures
• DIP and PIP arthrodeses
APTUS® Radius 2.5 group:
• Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures
• Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions.

APTUS® Ulna Plates
APTUS® Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.

APTUS® Wrist 2.5 System

APTUS® Wrist 2.5 System is indicated for use in hand and forearm fractures, osteotomies and arthrodeses.

APTUS® Wrist Arthrodesis Plates
APTUS® Wrist Arthrodesis Plates are indicated for wrist arthrodesis.

APTUS® Forearm Shaft Plates
APTUS® Forearm Shaft Plates are indicated for management of fractures and osteotomies of the radius and ulna shaft.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared on: 2023-08-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medartis AG
Applicant Address	Hochbergerstrasse 60E Basel 4057 Switzerland
Applicant Contact Telephone	+41 61 6333434
Applicant Contact	Ms. Claudia De Santis
Applicant Contact Email	claudia.desantis@medartis.com
Correspondent Name	Medartis Inc.
Correspondent Address	1195 Polk Drive Warsaw IN 46582 United States
Correspondent Contact Telephone	610-731-8650
Correspondent Contact	Ms. Chelsea Kozior
Correspondent Contact Email	chelsea.kozior@medartis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Sterile Products of the APTUS System
Common Name	Plate, Fixation, Bone (Primary) / Screw, Fixation, Bone / Pin, Fixation, Smooth
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	HRS (Primary) / HWC / HTY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K051567	APTUS® Titanium Fixation System	HRS
K090983	APTUS® 2.0/2.3 Four Corner Fusion Plates	HRS
K092038	APTUS® K-Wire System	HTY
K102537	APTUS® 1.5 TriLock	HRS
K103332	APTUS® Ulna System	HRS

K142906	APTUS® Wrist 2.5 System	HRS
K172170	APTUS® Wrist 2.5 System	HRS
K192297	APTUS® Wrist Arthrodesis System	HRS
K193554	APTUS® Forearm Shaft Plates	HRS
K191848	APTUS® Wrist Spanning Plates 2.5 (Reference Device)	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Sterile Products of the APTUS System is a plating, screw, and K-wire system for internal fixation of the bones of the hand, wrist, and/or forearm. All plates have anatomical designs that are appropriate to their intended use. The subject device plates include screw holes designed to accommodate appropriately sized bone screws.

Sterile Products of the APTUS System plate, screw, and K-wire system are the same in design as the previously cleared predicate and additional predicate devices. The overall dimensions of the subject device plates have the same lengths, widths, and thicknesses as the previously cleared predicate and additional predicate device. The subject device screws have the same design as the previously cleared Medartis APTUS Screws under K051567, K103332, and K142906. These include both locking (TriLock) and non-locking (cortical) screws. The subject device K-wires have the same design as the previously cleared APTUS K-Wires System under K092038. The K-wires are provided with a diameter of 1.2, 1.6, or 1.8 mm. All have a length of 150 mm. Single-ended trocar points are provided in 1.2 mm and 1.6 mm diameters, and single-ended bayonet (lancet) points are provided at all 3 diameters.

This submission includes all plates, screws, and K-wires that have been previously cleared under the predicate or additional predicate devices by Medartis AG, however, they will be provided in a sterile condition.
All subject device plates are manufactured from unalloyed titanium conforming to ASTM F67.
All subject device screws are manufactured from titanium alloy conforming to ASTM F136.
All subject device K-wires are manufactured from stainless steel conforming to ASTM F138.

All subject devices are associated with the predicate device and/or an additional predicate device mentioned in the predicates and product list sections.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The APTUS® Titanium Fixation System
The APTUS® Titanium Fixation System is indicated for use in hand and forearm fractures, osteotomies and arthrodeses.
APTUS® Hand group:
- Management of the fractures of the distal, middle and proximal phalanges and metacarpals
- Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft fractures, comminuted fractures, dislocation fractures, avulsion fractures
- DIP and PIP arthrodeses

APTUS® Radius 2.5 group:
- Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures
- Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions.

APTUS® 2.0/2.3 Four Corner Fusion Plate
The APTUS® 2.0/2.3 Four Corner Fusion Plate, an addition to the APTUS® Titanium Fixation System, is designed specifically for fusion of carpal bones including: hamate, capitate, lunate, triquetrum and is for use in patients suffering pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis. The fusion plate is used in conjunction with locking and non-locking screws that fix the plate to the carpal bones of the hand.

APTUS® K-Wire System
The APTUS® K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

APTUS® 1.5 TriLock
The APTUS® 1.5 TriLock is indicated for use in hand and forearm fractures, osteotomies and arthrodeses.
APTUS® Hand group:
• Management of the fractures of the distal, middle and proximal phalanges and metacarpals
• Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft fractures, comminuted fractures, dislocation fractures, avulsion fractures
• DIP and PIP arthrodeses
APTUS® Radius 2.5 group:
• Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures
• Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions.

APTUS® Ulna Plates
APTUS® Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna.

APTUS® Wrist 2.5 System
APTUS® Wrist 2.5 System is indicated for use in hand and forearm fractures, osteotomies and arthrodeses.

APTUS® Wrist Arthrodesis Plates
APTUS® Wrist Arthrodesis Plates are indicated for wrist arthrodesis.

APTUS® Forearm Shaft Plates
APTUS® Forearm Shaft Plates are indicated for management of fractures and osteotomies of the radius and ulna shaft.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has the same intended use and the same or similar Indications for Use as the predicate cleared under K051567 or associated additional predicate device cleared under K090983, K092038, K102537, K103332, K142906, K172170, K192297, or K193554.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device and/or the associated additional predicate devices. The subject and the predicate devices are all manufactured from the same materials (Unalloyed titanium, ASTM F67, grade 4; Ti-6Al-4V alloy, ASTM F136; and stainless steel, ASTM F138). The subject and predicate devices share the same design characteristics. The subject device has modified packaged to be provided sterile to the end user. The subject device also has modifications to the sterilization process to be provided sterile to the end user. The device modifications that are the subject of this submission, previously cleared under the reference device submission, do not raise any new questions of safety or effectiveness.

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

Performance Data
An analysis of the risk documentation and an engineering analysis was performed. These determined that the original testing of the sterilization process, previously cleared in the reference device submission under K191848, and the subsequent device performance is not adversely affected by the modifications to the subject device. The results of the analysis demonstrated the modified sterility and packaging are substantially equivalent to the predicate devices.

Non-clinical testing data referenced and relied upon to demonstrate substantial equivalence included: sterilization validation according to ISO 11137-1, ISO 11137-2, and ISO 11137-3. Sterile barrier shelf life testing according to ISO 11607-1, ISO 11607-2, ASTM F1980, ASTM D4332, ASTM D4169, ASTM F2096, DIN EN 868-5, and ASTM F88/F88M.

The subject device is manufactured from the same materials using identical manufacturing processes as their associated predicate device. There is no change to the type and duration of tissue contact for the subject device from the associated predicate device. The device modification, changing the sterilization method, was previously cleared under the reference device submission. Therefore, the device modification, that is the subject of this submission, is not expected to impact the biological response.

Clinical data is not provided in this submission.

Conclusion
In summary, the Sterile Products of the APTUS System has the following similarities to the predicate device and additional predicate devices :

- has the same intended use and the same or similar indications for use ,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has modified packaging so the device can be provided to the end user in a sterile condition.

The device modifications do not raise any new questions of safety and effectiveness of the subject device. Therefore, the Sterile Products of the APTUS System is substantially equivalent to the predicate devices with respect to intended use, operating principles, and technical characteristics.