August 30, 2023

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

Re: K232324
Trade/Device Name: StealthFix Intraosseous Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR, HWC
Dated: August 2, 2023
Received: August 3, 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,

Christopher Ferreira -S

for

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K232324

Device Name

StealthFix Intraosseous Fixation System

Indications for Use *(Describe)*

The StealthFix Intraosseous Fixation System is indicated for fixation of bone fractures, fusions, or for bone reconstructions, including:

- Arthrodesis in hand or foot surgery
- Mono or bi-cortical osteotomies in the foot or hand
- Fracture management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

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.

510(k) Summary

Prepared on: 2023-08-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medartis Inc.
Applicant Address	1195 Polk Drive Warsaw IN 46582 United States
Applicant Contact Telephone	610-731-8650
Applicant Contact	Ms. Chelsea Kozior
Applicant Contact Email	Chelsea.Kozior@medartis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	StealthFix Intraosseous Fixation System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Staple, Fixation, Bone
Regulation Number	888.3030
Product Code	JDR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220181	StealthFix Intraosseous Fixation System	JDR

Device Description Summary

21 CFR 807.92(a)(4)

The StealthFix Intraosseous Fixation System is an orthopedic intraosseous staple system consisting of staple and screw implants. The staples consist of two legs or posts connected by a bridge. The staples are available in post diameters of 2.5mm(mini), 3.5mm(small) and 4.5mm(standard). The 2.5mm staples are provided with a bridge span of 10mm and range in post length from 8mm to 12mm. The 3.5mm staples are provided with a bridge span of 15mm and range in post length from 14mm to 20mm. The 4.5mm staples are available in bridge spans of 15mm and 20mm and range in post length from 14mm to 32mm. The system provides crossing screws for optional fixation with the standard staple implants. Standard staples are designed with a screw slot to accept a crossing screw. The screws are available partially and fully threaded and are 3.5mm in diameter with lengths ranging from 16mm to 38mm in 2mm increments. The partially threaded screws are headed. The fully threaded screws are available headed and headless. The system provides accessory instruments designed for preparation of the implant site and insertion of implants into bone, including implant specific inserters and targeting arms. The implants of the system are available packaged both sterile and non-sterile for single use. The instruments are provided non-sterile, reusable or single use, and must be cleaned and sterilized by the end user prior to use. The system also provides some instruments sterile packaged, individually and in sets. Sterile instruments are for single use only.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The StealthFix Intraosseous Fixation System is indicated for fixation of bone fractures, fusions, or for bone reconstructions, including:

- Arthrodesis in hand or foot surgery
- Mono or bi-cortical osteotomies in the foot or hand
- Fracture management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

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

The subject device has the same intended use and Indications for Use as the predicate cleared under K220181.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device staple implants are identical in design and materials to the predicate device cleared under K220181.
The subject device screw implants and instruments have no change in materials. All screw implants are manufactured from Ti-6Al-4V alloy conforming to ASTM F136. The subject device instruments are manufactured using Stainless Steel in conformance with ASTM F899.
The subject device uses the same operating principles as the predicate device.
The subject device modifications are to provide additional screw implants and to modify the design of system instrumentation. The predicate device contains only partially threaded screws whereas the subject device contains both partially and fully threaded 3.5mm screws. These device modifications do not raise different types of safety and effectiveness questions. The design control process according to 21 CFR 820.30 was followed to ensure the device modifications do not create a new worst case and function as intended.

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

Non-Clinical Testing:
Endotoxin testing was performed using the Limulus Amebocyte Lysate (LAL) method according to AAMI ST72, USP 161 and USP 85. Results met the Endotoxin limit of ≤20 EU per device. Mechanical testing was not required to demonstrate substantial equivalence of the StealthFix Intraosseous Fixation System to the predicate device. An engineering analysis was performed to compare the subject and predicate screws to demonstrate that the new screws do not create a new worst case for screw mechanical strength (cross sectional area) or screw fixation (thread substrate interface area). Device usability was evaluated through cadaveric testing.

Clinical Testing:
Clinical testing was not necessary to demonstrate substantial equivalence of the StealthFix Intraosseous Fixation System to the predicate device.

Conclusions:
The StealthFix Intraosseous Fixation System is substantially equivalent to the predicate devices regarding its intended use, material, design, sizes, and mechanical properties. Differences between the subject device system and the predicate device systems do not raise new types of safety and effectiveness questions.