December 14, 2023

Jeil Medical Corporation
Dajung Lee
RA Specialist
702-703-704-705-706-804-805-807-812-815-ho, 55
Digital-ro 34-gil, Guro-gu
Seoul, 08378
Korea, South

Re: K231887
Trade/Device Name: ARIX Ankle Distal Tibia 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, HWC
Dated: November 7, 2023
Received: November 13, 2023

Dear Dajung Lee:

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, 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)*
K231887

Device Name
ARIX Ankle Distal Tibia System

Indications for Use *(Describe)*
The ARIX Ankle Distal Tibia System(Ankle fusion) is indicated for facilitating arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints.

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.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

7th December 2023

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
  - Address: 702,703,704,705,706,804,805,807,812,815-ho, 55, Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
- Contact Name: Dajung Lee / RA Specialist
  - Telephone No.: +82 2 850 3591
  - Fax No.: +82 2 850 3536
  - Email Address: dajunglee@jeilmed.co.kr
- Registration Number: 3004049923
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name; ARIX Ankle Distal Tibia System
- Common Name; - Plate, Fixation, Bone (Primary)
  - Screw, Fixation, Bone
- Classification Name; - Single/multiple component metallic bone fixation appliances and Accessories (Primary)
  - Smooth or threaded metallic bone fixation fastener
- Classification Panel; Orthopedic
- Classification regulation; 21 CFR 888.3030 (Primary), 21 CFR 888.3040
- Product code; HRS (Primary), HWC
- Device Class; II

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The legally marketed device(s) to which substantial equivalence is claimed is/are:

Primary Predicate Device	K181067 – AlignX Ankle Fusion System, Extremity Medical, LLC.
Secondary Predicate Device	K141735 – Arthrex Ankle Fusion Plating System, ARTHREX, INC.
Reference Device	K202912 – ARIX Ankle Distal Tibia System, Jeil Medical Corporation

There are no significant differences between the subject device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in intended use and technological characteristics as internal fixation components.

5. Description of the Device [21 CFR 807.92(a)(4)]

The ARIX Ankle Distal Tibia System is rigid fixation consisting of plates and screws in various configurations, shapes, and sizes.

The ARIX Ankle Distal Tibia System is made of Titanium Alloy (Ti-6Al-4V), which meet ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility.

6. Indications for use [21 CFR 807.92(a)(5)]

The ARIX Ankle Distal Tibia System(Ankle fusion) is indicated for facilitating arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

ARIX Ankle Distal Tibia System, Bone Plate, Bone Screw:

Based on the technological feature comparison, the subject device was found that there are no significant differences between the subject device and predicate devices that would adversely affect the use of the product and it is substantially equivalent to predicate device in technological characteristics.

Non-Clinical Test Summary:

Bench tests were conducted to ensure the safety and effectiveness of the device as well as to demonstrate substantial equivalence to the predicate device. The test results demonstrated that the subject device complies with the following standards:

- ASTM F382, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F543, Standard Specification and Test Methods for Metallic Medical Bone Screws

The results of this testing indicate that the ARIX Ankle Distal Tibia System is equivalent to predicate device.

Clinical Test Summary

No clinical studies were considered necessary and performed.

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8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

Based on the submitted information in this premarket notification, the subject device is substantially equivalent to the predicate devices in terms of:

- Intended use
- Technological characteristics (Design features, Material, Surface Treatment, Sterilization methods, Biocompatibility and Performance)

The subject device has met the performance, safety, and effectiveness of the device for its intended use.

9. Conclusion [21 CFR 807.92(b)(3)]

In all respects, the ARIX Ankle Distal Tibia System is substantially equivalent to the legally marketed device. Above all, the subject device has equivalent intended use and technological characteristics. Further, nonclinical verification and validation to determine substantial equivalence provide additional evidence that subject device is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.