October 29, 2020

Jeil Medical Corporation
Ahhyeon Woo
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: K202912
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: September 25, 2020
Received: September 29, 2020

Dear Ahhyeon Woo:

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, MPH
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)*

K202912

Device Name

ARIX Ankle Distal Tibia System

Indications for Use *(Describe)*

The ARIX Ankle Distal Tibia System is intended for fixation of complex intra- and extraarticular fractures and osteotomies of the distal tibia including distal tibia fractures in combination with diaphyseal fracture.

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."

FORM FDA 3881 (6/20) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

JEILMEDICAL
702·703·704·705·706·804·805·807·812·815-ho, 55,
Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
Tel : +82 2 850 3591 / Fax : +82 2 850 3536

510(k) Summary

[As required by 21 CRF 807.92]

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

25th September 2020

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-ro34-gil, Guro-gu, Seoul, 08378, Korea
- Contact Name: Ahhyeon Woo / RA Specialist
  - Telephone No. : +82 2 850 3591
  - Fax No. : +82 2 850 3536
  - Email Address : uah0606@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: Bone Plate and Bone Screw
- Classification Name: Plate, Fixation, Bone
- Classification Description: Single/multiple component metallic bone fixation appliances and accessories
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3030
- Product Code: HRS, HWC
- Device Class: II

JEILMEDICAL
702·703·704·705·706·804·805·807·812·815-ho, 55,
Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
Tel : +82 2 850 3591 / Fax : +82 2 850 3536

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

The identified predicate device within this submission are shown as follow;

Primary Predicate	K170313 - ARIX Ankle Distal Tibia System Jeil Medical Corporation
Other Predicates	K172008 - ARIX Humerus System Jeil Medical Corporation
	K001945 - SYNTHES (USA) MEDIAL DISTAL TIBIA PLATES SYNTEHS(USA)

There are no significant differences between the subject device and the predicate device (K170313) that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, and operational principles 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.

The plates vary essentially through different lengths and number of plate holes. The screws are self-tapping, which are applied with the reconstruction locking screws together. The Screws are provided with diameter 3.5mm and 4.0mm. And Screws are provided with lengths from 10mm to 110mm.

JEILMEDICAL
702·703·704·705·706·804·805·807·812·815-ho, 55,
Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
Tel : +82 2 850 3591 / Fax : +82 2 850 3536

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

The ARIX Ankle Distal Tibia System is intended for fixation of complex intra- and extraarticular fractures and osteotomies of the distal tibia including distal tibia fractures in combination with diaphyseal fracture.

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

ARIX Ankle Distal Tibia System, Bone Plate:
Based on a technical feature comparison, the subject device was found to be similar to all predicate devices with regard to design and materials. The subject plates also have a variable locking feature, similar to the design used in the predicate device (K170313).

ARIX Ankle Distal Tibia System, Bone Screw:
ARIX Ankle Distal Tibia System Screws consist of the cleared “ARIX Ankle Distal Tibia System (K170313)” and “ARIX Humerus System (K172008)”. The new added model, 40-SA series screw share similar head, neck and thread designs that are currently cleared under the reference device (K172008).

Non-Clinical Test Summary:
Bench tests were conducted to verify that the subject device met all design specifications. The test result 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 Method for Metallic Medical Bone Screws

The following tests were performed with the predicate device:

- Plate
  - 4-Point Bending Test
  - 4-Point Fatigue Test

- Screw
  - Driving Torque Test
  - Torsion Test
  - Axial Pull-out Test

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.

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

When compared to the predicate device (K170313), the ARIX Ankle Distal Tibia System presented in this submission has the same:

- Indication for Use
- Technological characteristics
- Operating principle

JEILMEDICAL
702·703·704·705·706·804·805·807·812·815-ho, 55,
Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
Tel : +82 2 850 3591 / Fax : +82 2 850 3536

- Design features
- Performance
- Biocompatibility
- Materials
- Method of sterilization

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

In all respects, the ARIX Ankle Distal Tibia System is the equivalent of currently marketed devices. This device is made of same materials and has similar dimensions and characteristics. The ARIX Ankle Distal Tibia System is manufactured from the titanium alloy that is used generally in this kind of bone plate and bone screw system. Based on the information submitted, ARIX Ankle Distal Tibia System is substantially equivalent to the currently marketed predicate devices.