DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Jeil Medical Corporation
Sejin Ryu
RA Specialist
#702, Kolon Science Valley 2nd 55
Digital-ro 34, Guro-gu
Seoul, 152-728 Korea

July 27, 2017

Re: K170313
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: June 30, 2017
Received: July 3, 2017

Dear Sejin Ryu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K170313

Device Name: ARIX Ankle Distal Tibia System

Indications for Use:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

[As required by 21 CFR 807.92]

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

26 January 2017

2. Submitter's Information [21 CFR807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
  - Address: #702, Kolon Science Valley 2nd
    811, Guro-dong, Guro-gu
    Seoul, 152-728, Korea
- Contact Name: Sejin RYU / RA Specialist
  - Telephone No. : +82 2 850 3500
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  - Email Address : rsj@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 Screw
- Classification Name: Plate, Fixation, Bone / Screw, Fixation, Bone
- Classification Description: Single/multiple component metallic bone fixation appliances and accessories
  Smooth or threaded metallic bone fixation fastener
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3030
  21 CFR 888.3040

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- Product Code: HRS / HWC
- Device Class: II

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

The identified predicate devices within this submission are shown as follows:

- Primary Predicate Devices

- 510(k) Number: K013248
- Device Name: Synthes LCP Distal Tibia Plates

- Additional Predicate Devices

- 510(k) Number: K163044
- Device Name: Ortholoc 3Di Ankle Fracture Plating System

- 510(k) Number: K103705
- Device Name: Low Profile Screws

- Reference Predicate Devices

- 510(k) Number: K112812
- Device Name: LeForte System

- 510(k) Number: K151468
- Device Name: ARIX Wrist System

- 510(k) Number: K131311
- Device Name: ARIX Foot System

- 510(k) Number: K132876
- Device Name: ARIX Hand Locking System

There are no significant differences between the Model ARIX Ankle Distal Tibia System and the predicate devices (K013248, K163044, K103705) 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.

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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, as follows:

	Plate	Cortical Screw	Locking Screw
Type/ Configuration	Medial Type	28-SO-L Series 35-SO-L Series	28L-SO-L Series 35L-SO-L Series
	Anterolateral Type		
	T Type		
Material	ASTM F 136, Titanium Alloy (Ti-6Al-4V)	ASTM F 136, Titanium Alloy (Ti-6Al-4V)	ASTM F 136, Titanium Alloy (Ti-6Al-4V)

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 Cortical Screws & locking screws are provided with diameter 2.8 mm to 3.5 mm and lengths from 8 mm to 80 mm.

ARIX Ankle Distal Tibia System is provided as Gold color which is casted according to the anodizing technique while apply 5 V electric energy to the titanium.

It also includes various manual surgical instruments, such as drill bits, counter sink, depth gauge, compression, drill guide, drill sleeve, guide pin, bender and screw driver handle.

The ARIX Ankle Distal Tibia System not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The sterilization method is presented in the instruction, which was validated per ISO 17665-1: 2006 Sterilization of health care products – Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

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

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

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

ARIX Ankle Distal Tibia System, Bone Plates: Based on a technical feature comparison, the subject device was found to be similar to predicate devices with regard to design and materials. The subject plates also have a locking feature, similar to the design used in the predicate device (K013248).

ARIX Ankle Distal Tibia System, Bone Screws: They share similar head, neck, and thread designs as the screws that are currently cleared under the predicate device (K013248).

Non-Clinical Test Summary:

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F 382-14, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F 543-13, Standard Specification and Test Methods for Metallic Medical Bone Screws

The following tests were performed with the predicate device:

- Plates
  - Bending strength test per ASTM F382
  - Bending fatigue test per ASTM F382

- Screw
  - Driving torque test per ASTM F543
  - Torsion test per ASTM F543
  - Axial pull out test per ASTM F543

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]

When compared to the predicate device (K013248) the ARIX Ankle Distal Tibia System presented in this submission has the same:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biocompatibility
- Materials
- Method of sterilization and sterility assurance level

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 the same materials and has similar dimensions and characteristics. This device is manufactured from titanium that is used generally in this kind of bone plate/screw system. This device, ARIX Ankle Distal Tibia System, is substantially equivalent in design, material, and function to the predicate device.