



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Jeil Medical Corporation  
Sejin RYU  
RA Specialist  
#702,703,704,705,706,804,805,807,812-ho,55  
Digital-ro34-gil, Guro-gu, Seoul, 152-728  
Korea

August 17, 2017

Re: K170979  
Trade/Device Name: ARIX Ankle Fibula Hook Plate 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 21, 2017  
Received: July 21, 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

## Indications for Use

510(k) Number (if known):

Device Name: ARIX Ankle Fibula Hook Plate System

Indications for Use:

The ARIX Ankle Fibula Hook Plate System is intended for use in internal fixation of the distal fibula.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## **510(k) Summary**

[As required by 21 CFR 807.92]

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

16 August, 2017

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

- Name of Sponsor: Jeil Medical Corporation
  - Address: 702-703-704-705-706-804-805-807-812-ho,55  
Digital-ro34-gil, Guro-gu, Seoul, 152-728, Korea
  
- Contact Name: Sejin RYU / RA Specialist
  - Telephone No. : +82 2 850 3500
  - Fax No. : +82 2 850 3536
  - 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 Fibula Hook Plate System
  
- Common Name: Bone plates
  
- Classification Name: Single/Multiple Component Metallic Bone Fixation  
Appliances and Accessories
  
- Classification Panel: Orthopedic
  
- Classification Regulation: 21 CFR 880.3030
  
- Product Code: HRS
  
- 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:

- 510(k) Number: K152158
- Applicant: Jeil Medical Cororation
- Common Name: Plate, Fixation, Bone
- Device Name: ARIX Ankle System
  
- 510(k) Number: K081284
- Applicant: Howmedica Osteonics Corp.
- Common Name: Plate, Fixation, Bone
- Device Name: VariAx Distal Finula Plate

There are no significant differences between the Model ARIX Ankle Fibula Hook Plate System and the predicate devices 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 Fibula Hook Plate System is rigid fixation consisting of plates in various configurations, shapes and sizes, as follows:

	Plate
Type/ Configuration	Hook Plate
Material	ASTM F67, Pure Titanium Gr4

The ARIX Ankle Fibula Hook Plate System is made of Pure Titanium Gr4 which meets ASTM F67, Standard Specification for Unalloyed Titanium, 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 plate features locking holes and non-locking holes which accept 3.5mm cortex screws and locking screw. (Previously cleared K152158, K161864)

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.

ARIX Ankle Fibula Hook Plate 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 Fibula Hook Plate System is intended for use in internal fixation of the distal fibula.

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

**ARIX Ankle Fibula Hook Plate:** 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 (K152158, K081284).

### **Non-Clinical Test Summary:**

An engineering analysis was performed to evaluate the engineering rationale of predicate compared to the subject device plate.

The test results demonstrated that the proposed device complies with the following standards:

- ASTM F 382, Standard Specification and Test Method for Metallic Bone Plates

The following tests were performed with the predicate device:

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

The engineering rationale indicates that the ARIX Ankle Fibula Hook Plate System is equivalent to the 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 (K152158, K081284) the ARIX Ankle Fibula Hook Plate 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 Fibula Hook Plate 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 Fibula Hooke Plate System, is substantially equivalent in design, material, and function to the predicate device.