



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Jeil Medical Corporation  
Jiwon KANG  
RA Specialist  
702•703•704•705•706•804•805•807•812-ho, 55,  
Digital-ro34-gil, Guro-gu  
Seoul-City, 152-728  
Republic of KOREA

September 28, 2015

Re: K152158  
Trade/Device Name: ARIX Ankle System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and  
Accessories  
Regulatory Class: Class II  
Product Code: KTT  
Dated: August 26, 2015  
Received: August 27, 2015

Dear Ms. Jiwon KANG:

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 yours,

**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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## Indication for Use

510(k) Number (if known):

Device Name: ARIX Ankle System

Indication for Use:

The ARIX Ankle System(Fibula) 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)

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## 510(k) Summary

[As required by 21 CFR 807.92]

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

21 August 2015

### 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-ho, 55  
Digital-ro34-gil, Guro-gu, Seoul, 152-728, Korea
- Contact Name: Jiwon KANG (Ms.) / RA Specialist
  - Telephone No. : +82 2 850 3500
  - Fax No. : +82 2 850 3525
  - Email Address : jwkang@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 System
- Common Name: Bone plates and screws
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3030
- Product Code: KTT
- Device Class: II



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

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

- 510(k) Number: K081284
- Applicant: HOWMEDICA OSEONICS CORP.
- Common Name: plate, fixation, bone
- Device Name: VariAX™ Distal Fibula Plate

There are no significant differences between the Model ARIX Ankle 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 System is rigid fixation consisting of plates and screws in various configurations, shapes and sizes as follow;

	<b>Straight Plate</b>	<b>Lateral Plate</b>	<b>Cortical Screw</b>	<b>Locking Screw</b>
<b>Type Configuration</b> /	35-DLST Series	35-DLFI Series	35-HF Series	35L-HF Series
<b>Material</b>	ASTM F 67 Pure Titanium	ASTM F 67 Pure Titanium	ASTM F 136 Titanium Alloy (Ti-6Al-4V)	ASTM F 136 Titanium Alloy (Ti-6Al-4V)

The ARIX Ankle System is made of Pure Titanium and Titanium Alloy (Ti-6Al-4V), which meet ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications, and 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 cortical screws, locking screws diameter is 3.5mm lengths is from 10mm to 70mm. It also includes various manual surgical instruments, as drill guides, drill bits, driver shafts, depth gauge, bender and handbody etc.,. The ARIX Ankle 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.

This device performance is not adversely affected by aging or storage conditions since this device is to be sterilized at the hospital before use and also to be single use.



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## 6. Intended Use [21 CFR 807.92(a)(5)]

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

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

**ARIX Ankle System, Bone Plates:** 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 poly axial locking feature, similar to the design used in the predicate devices (K081284 ).

**ARIX Ankle System, Bone Screws:** They share similar head, neck and thread designs as the smaller screws that are currently cleared under the predicate devices (K081284).

### **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 382-99, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws

The following tests were performed with the predicate devices:

- Plates
  - Dimension test
  - Single Cycle Bending test per ASTM F382
  - Bending Fatigue test per ASTM F382
- Screws
  - Dimension test
  - Driving torque test per ASTM F543-07
  - Axial pull-out test per ASTM F543-07
  - Torsion test per ASTM F543-07

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

### **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 devices (K081284), the ARIX Ankle 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 the respects, the ARIX Ankle 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 material of the Pure Titanium and Titanium Alloy, Unalloyed titanium and Wrought titanium alloy that is used generally in this kind of bone plate/screw system. This device, ARIX Ankle System, is substantially equivalent in design, material, and function to the predicate devices.