March 4, 2020

Jeil Medical Corporation
Jonghwan Kim
RA Specialist
702, 703, 704, 705, 706, 804, 805, 807, 812-ho, 55
Digital-ro34-gil, Guro-gu
Seoul, 08378 Korea

Re: K193616
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: HRS, HWC
Dated: January 29, 2020
Received: February 3, 2020

Dear Jonghwan Kim:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193616

Device Name
ARIX Ankle System

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

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 CRF 807.92]

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

23th December 2019

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: Jonghwan Kim / RA Specialist
  - Telephone No. : +82 2 850 3524
  - Fax No. : +82 2 850 3536
  - Email Address : hwan0708@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: Plate, Fixation, Bone
- Classification Name: 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

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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: K152158
- Applicant: Jeil Medical Corporation
- Common Name: Bone Plate and Bone Screw
- Device Name: ARIX Ankle System

There are no significant differences between the subject device and the predicate devices (K152158) 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.

The ARIX Ankle System is made of Unalloyed 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 screws are self-tapping, which are applied with the reconstruction locking screws together. The Locking Screws are provided with diameter 3.5mm and Cortical Screws are provided with diameter 3.5mm. And both are provided with lengths from 10 mm to 70 mm.

6. Indication for 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:
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 (K152158). The subject plates and screws are manufactured from the same materials as the predicate. The subject plates are similar in lengths, widths and thicknesses and screws are available in similar types, diameters and lengths. The subject plates differ because compression slots were added to the plate shaft and because they contain additional screw holes on the head of the fibula plates. The screw head geometry also slightly differs from the predicate.

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Non-Clinical Test Summary:
An engineering analysis was submitted to demonstrate that the subject plates do not present a new worst case for ASTM F382 bending performance. An engineering analysis was provided to demonstrate why the screws do not present a new worst case for ASTM F543 testing. The results of the verification activities indicate that the ARIX Ankle System is equivalent to predicate device.

Clinical Test Summary:
No clinical studies were considered necessary and performed.

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

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