Jeil Medical Corporation
Jiwon Song
RA Specialist
#702, Kolon Science Valley 2nd
55, Digital-ro 34, Guro-gu
Seoul, 152-728 KR

Re: K170705
Trade/Device Name: ARIX Wrist 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 7, 2017
Received: September 8, 2017

Dear Ji Song:

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 (DICE) 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 (DICE) 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
Indication for Use

510(k) Number (if known): K170705

Device Name: ARIX Wrist System

Indication for Use:

The ARIX Wrist System(Radius) is intended for use in forearm fractures, osteotomies and arthrodesis. The ARIX Wrist System(Ulna) is intended for fractures and osteotomies, in particular for the ulna.

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)
510(k) Summary

[As required by 21 CRF 807.92]

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

March 06, 2017

2. Submitter’s Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
  - Address: #702, Kolon Science Valley 2nd
  55, Digital-ro 34, Guro-gu
  Seoul, 152-728, Korea

- Contact Name: Jiwon Song / RA Specialist
  - Telephone No.: +82 2 850 3587
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  - Email Address: sjw@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 Wrist 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

- 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 follow;

- 510(k) Number: K151468
- Applicant: Jeil Medical Corporation
- Device Name: ARIX Wrist System
There are no significant differences between the subject system and the predicate devices (K151468, K092247, K102694) in design, function, materials, and operational principles as internal fixation components.

- **Reference Predicate Devices**

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

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

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

5. **Description of the Device [21 CFR 807.92(a)(4)]**

The ARIX Wrist System consists of plates designed for the Ulna and Radius. The ARIX Wrist 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 Aluminium-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 vary essentially through different lengths and diameters. The screws in this system are available from 2.0mm to 2.8mm. It also includes various manual surgical instruments, as drill guides, drill bits, driver shafts, depth gauge, bender and hand body. The ARIX Wrist System not provided sterile. It is required to be sterilized via autoclave using the validated method prior to surgery.

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

The ARIX Wrist System(Radius) is intended for use in forearm fractures, osteotomies and arthrodesis. The ARIX Wrist System(Ulna) is intended for fractures and osteotomies, in particular for the ulna.

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

ARIX Wrist 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 (K151468, K090047, K102694).
**ARIX Wrist System, Bone Screws:** They share similar head, neck and thread designs with predicate devices (K151468).

**Non-Clinical Test Summary:**
Bench tests were conducted to verify that the proposed device had substantially equivalent performance compared to a predicate. The test results demonstrated that the proposed device complies with the following standards:

- **Plate**
- **Screw**
  - ASTM F 543, Standard Specification and Test Methods for Metallic Medical Bone Screws

The following tests were performed with the predicate device:

- **Plate**
  - Dimension test per ASTM F382
  - 4-Point Bending test per ASTM F382
  - Fatigue test per ASTM F382
- **Screw**
  - Dimension test per ASTM F543
  - Driving torque test per ASTM F543
  - Axial pull-out test per ASTM F543
  - Torsion test per ASTM F543

The results of this testing indicate that the ARIX Wrist 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]**

The subject device has the same device characteristics as our previously cleared predicate device. They have the same intended use, raw material, and use concept and employ the same anodization and sterilization method. The differences are in shape and dimensions; however, the performance test data provided in this submission proves the subject device is safe and effective and performed substantially equivalent to the predicates.

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

Based on the information provided in this premarket notification Jeil Medical Corporation concludes that ARIX Wrist System Bone Plate & Screw is as safe and as effective as the predicate devices.