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

November 30, 2017

Re: K172008
Trade/Device Name: ARIX Humerus 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: October 19, 2017
Received: October 26, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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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Indication for Use

510(k) Number (if known): K172008

Device Name: ARIX Humerus System

Indication for Use:
ARIX Humerus System is indicated for fractures, fracture dislocations, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

[As required by 21 CRF 807.92]

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

29 November 17

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: Sejin RYU / RA Specialist
  - Telephone No.: +82 2 850 3500
  - Fax No.: +82 2 850 3536
  - Email Address: rsj@jeilmed.co.kr
- Registration No.: 3004049923
- Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: ARIX Humerus System
- Common Name: Bone Plate and Bone Screw
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 880.3030
- Product Code: HRS, HWC
- Device Class: II

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

The identified predicate devices within submission are shown as follows:

- 510(k) Number: K011815
- Applicant: Synthes (USA)
- Device Name: SYNTHES LCP PROXIMAL HUMERUS PLATES

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- 510(k) Number: K171285
- Applicant: Jeil Medical Corporation
- Common Name: Bone Plate, Bone Screw
- Device Name: ARIX Diaphysis System

- **Reference Predicate Device**

- 510(k) Number: K151468
- Applicant: Jeil Medical Corporation
- Common Name: Bone Plate, Bone Screw
- Device Name: ARIX Wrist System

- 510(k) Number: K152158
- Applicant: Jeil Medical Corporation
- Common Name: Bone Plate, Bone Screw
- Device Name: ARIX Ankle System

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

	Plate	Cortical Screw	Locking Screw
Type/ Configuration	35-PLHU series	35-SO-L series	35L-SO-L series 40L-SA series 45L-CO series
Material	ASTM F 67, Unalloyed Titanium	ASTM F 136, Titanium Alloy (Ti-6Al-4V)	ASTM F 136, Titanium Alloy (Ti-6Al-4V)

The ARIX Humerus System is consists of plates and screws. The ARIX Humerus 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 h 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. It also includes various manual surgical instruments, as drill bits, driver shafts and depth gauge.

It also includes various manual surgical instruments, such as hand body, driver, drill bits, depth gauge, drill sleeve, forceps, drill guide block, sleeve handle and drill guide.

The ARIX Humerus 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.

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

ARIX Humerus System is indicated for fractures, fracture dislocations, osteomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

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

ARIX Humerus System Bone 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 (K011815)

ARIX Humerus System Bone Screw: They share similar head, neck, and thread designs as the screws that are currently cleared under the predicate device (K011815 and K171285).

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

The following tests were performed with the predicate device:

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

The results of this testing indicate that the ARIX Humerus 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)(a) and 807.92]

When compared to the predicate device (K011815, K171285) 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 Humerus 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 Humerus, is substantially equivalent in design, material, and function to the predicate device.