May 3, 2023

Jeil Medical Corporation
Bora Kim
RA Specialist
702, 703, 704, 705, 706, 804, 805, 807, 812, 815-ho,
55, Digital-ro 34-gil, Guro-gu
Seoul, 08378
Korea, South

Re: K230938
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: March 31, 2023
Received: April 3, 2023

Dear Bora 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 -S

Shumaya Ali, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230938

Device Name
ARIX Humerus System

Indications for Use *(Describe)*
The ARIX Humerus System is indicated for fractures, fracture dislocations, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

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)]

31th March 2023

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: Bora Kim / RA Specialist
  - Telephone No. : +82 2 850 3533
  - Fax No. : +82 2 850 3536
  - Email Address : borakim@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 Humerus System
- Common Name: ***Plate, Fixation, Bone / Screw, Fixation Bone***
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories ***(Primary)***, ***/ Smooth or threaded metallic bone fixation fastener***
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3030***(Primary),*** 21 CFR 888.3040
- Product Code: HRS***(Primary),*** HWC
- Device Class: II

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

The identified predicate devices within this submission ***are the only primary predicate device and*** are shown as follow;

- 510(k) Number: K172008
- Applicant: Jeil Medical Corporation
- Common Name: Bone Plate and Bone Screw
- Device Name: ARIX Humerus System

There are no significant differences between the subject device and the predicate devices (K172008) 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.

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, depth gauge.

The ARIX Humerus System is not provided sterile. It is required to be sterilized to reach a SAL of 10^{-6} by the hospital prior to surgery.

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

ARIX Humerus System is indicated for fractures, fracture dislocations, osteotomies 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 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 (K172008).

ARIX Humerus System, Bone Screw:
ARIX Humerus System is the same as the screws of the cleared ARIX Humerus System (K172008) without any changes.

Non-Clinical Test Summary:

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the subject device complies with the following standards:

- ASTM F382, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F543, 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)(1) and 807.92]

When compared to the predicate device (K152158), the ARIX Humerus System presented in this submission has the same:

- Indication for use
- Technical characteristics
- Operating Principle
- Design Features
- Performance
- Biocompatibility
- Materials
- Method of sterilization

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 same materials and has similar dimensions and characteristics. The ARIX Humerus 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 Humerus System is substantially equivalent to the currently marketed predicate devices.