September 15, 2020

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

Re: K201656
Trade/Device Name: ARIX Elbow 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: June 10, 2020
Received: June 18, 2020

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. 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

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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)*

K201656

Device Name

ARIX Elbow System

Indications for Use *(Describe)*

The ARIX Elbow System is intended for fractures and osteotomies of proximal radius, ulnar olecranon and distal humerus. The ARIX Proximal Radius Plate is intended for use in proximal radial fractures and osteotomies. The ARIX Olecranon Plate is intended for use in particular for ulna fractures and osteotomies. The ARIX Distal Humerus Plate is intended for use in distal humerus fractures, osteotomies and non-unions.

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)]

August 13, 2020

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: Sejin Ryu / RA Specialist
  - Telephone No.: +82 2 850 3583
  - Fax No.: +82 2 850 3536
  - Email Address: rsj@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 Elbow System
- Common Name; Plate, Fixation, Bone (Primary)
  Screw, Fixation, Bone
- Classification Name; Single/multiple component metallic bone fixation appliances and accessories
- Classification Panel; Orthopedic
- Classification regulation; 21 CFR 888.3030 (Primary),
  21 CFR 888.3040
- Product code; HRS (Primary),
  HWC
- Device Class; II

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

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

Primary Predicate	K090053 – APTUS 2.0 Radial Head System Medartis AG
Additional Predicates	K103332 – APTUS Ulna Plates Medartis AG K112560 – APTUS Distal Humerus System Medartis AG K063049 – Synthes Modular Mini Fragment LCP System Synthes (USA)
Reference Device	K170705 – ARIX Wrist System, Jeil Medical Corporation K170313 – ARIX Ankle Distal Tibia System, Jeil Medical Corporation K171285 – ARIX Diaphysis System, Jeil Medical Corporation K172008 – ARIX Humerus System, Jeil Medical Corporation

There are no significant differences between the subject device 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 Elbow System is consist of proximal radius plate, ulna olecranon plate, distal humerus plate and bone screw.

The ARIX Elbow 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 type and number of plate holes. The screws vary essentially through different lengths and diameters. It also includes various manual surgical instruments such as drill bits, drill sleeve and sleeve handle, drill guide, driver, depth gauge, bender, handle, driver shafts and depth gauge.

The ARIX Elbow 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)]

The ARIX Elbow System is intended for fractures and osteotomies of proximal radius, ulnar olecranon and distal humerus. The ARIX Proximal Radius Plate is intended for use in proximal radial fractures and osteotomies. The ARIX Olecranon Plate is intended for use in particular for ulna fractures and osteotomies. The ARIX Distal Humerus Plate is intended for use in distal humerus fractures, osteotomies and non-unions.

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

Bone Plate: Based on a technical feature comparison, the subject device was found to be similar to predicated devices with regard to design and materials. The subject plates also have locking feature, similar to the design used in the predicate device. (K090053, K103332, K112560)

Bone Screw: They share similar head, neck, and thread designs as the screws that are previously cleared under the predicate devices. (K063049, K170705)

Non-Clinical Test Summary:
Non-Clinical Test was conducted to verify that the subject device met all design specifications. The test result demonstrated that the subject device complies with the following standards:

- ASTM F543, Standard Specification and Test Method for Metallic Medical Bone Screws
- ASTM F382, Standard Specification and Test Method for Metallic Bone Plates

The results of this testing indicate that the ARIX Elbow 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 devices (K090053, K103332, K112560 and K063049), the ARIX Elbow System presented in this submission has the same:

- Indication for Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biocompatibility
- Materials
- Method of sterilization

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

In all respects, the ARIX Elbow 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 Elbow, is substantially equivalent in design, material, and function to the predicate device.