October 3, 2018

Jeil Medical Corporation
Seungyong Lee
RA Specialist
702,703,704,705,706,804,805,807,812,815-ho,55
Digital-ro34-gil, Guro-gu
Seoul, KR 08378

Re: K180972
Trade/Device Name: ARIX Clavicle 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 4, 2018
Received: September 4, 2018

Dear Seungyong Lee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Tejen D. Soni -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180972

Device Name

ARIX Clavicle System

Indications for Use *(Describe)*
The ARIX Clavicle System is indicated for the fixation of single, segmental and comminuted fractures, osteotomies, mal-unions, and non-unions of the clavicle.

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)]

11th April 2018

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: Seungyong Lee / RA Specialist
  - Telephone No. : +82 2 850 3533
  - Fax No. : +82 2 850 3536
  - Email Address : leesy@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 Clavicle System
- Common Name: Bone Plate and Bone Screw
- Classification Name: Plate, Fixation, Bone / Screw, Fixation, Bone
- Classification Description: 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;

Primary Predicate	K130116 - Superior Lateral Variax Clavicle Plate System Stryker Trauma AG Plate
Additional Predicates	K112111 - Acu-sinch Repair System And Acumed Suture Anchor Acumed LLC
	K170705 - ARIX Wrist System, K171285 - ARIX Diaphysis System Jeil Medical Corporation

There are no significant differences between the subject device and the predicate devices (K130116, K112111, K170705,K171285) 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 Clavicle System is rigid fixation consisting of plates and screws in various configurations, shapes and sizes.

The ARIX Clavicle System is made of Titanium Alloy (Ti-6AL-4V), which meet ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-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 2.5, 3.5mm and Cortical Screws are provided with diameter 3.5mm. And both are provided with lengths from 6 mm to 110 mm.

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

The ARIX Clavicle System is indicated for the fixation of single, segmental and comminuted fractures, osteotomies, mal-unions, and non-unions of the clavicle.

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

ARIX Clavicle 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 (K130116). The screws are similar in size compared to the predicates.

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Non-Clinical Test Summary:
Bench tests were 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 F382, Standard Specification and Test Method for Metallic Bone Plates
- ASTM F543, Standard Specification and Test Method for Metallic Medical Bone Screws

The following tests were performed with the predicate device:

- Plate
  - 4-Point Bending Test
  - 4-Point Fatigue Test

- Screw
  - Driving Torque Test
  - Torsion Test
  - Axial Pull-out Test

The results of this testing indicate that the ARIX Clavicle 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 (K130116), the ARIX Clavicle System presented in this submission has equivalent:

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

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

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