November 22, 2022

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

Re: K221412
Trade/Device Name: ARIX Rib 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 20, 2022
Received: October 21, 2022

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 -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)*
K221412

Device Name
ARIX Rib System

Indications for Use *(Describe)*
The ARIX Rib System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies.

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)]

November 22, 2022

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-ro 34-gil, Guro-gu, Seoul, 08378, Korea
- Contact Name: Sejin Ryu / RA Manager
  - 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 of Sponsor
  - Address: Same of Sponsor

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

Trade Name;	ARIX Rib System
Common Name;	Bone Plate and Bone Screw
Classification Name;	Plate, Fixation, Bone / Screw, Fixation, Bone
Classification Panel;	Orthopedic
Classification Regulation;	21 CFR 888.3030
Product Code;	HRS, HWC
Device Class;	II

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

The legally marketed device(s) to which substantial equivalence is claimed is/are:

Primary Predicate	K152253 – Biomet Microfixation RibFix Blu Thoracic Fixation System, Biomet Microfixation
Secondary Predicate	K113318 – ACUTE Innovations Modular RibLoc Fixation System, ACCUTE Innovations, LLC

Reference Device K181806 – ARIX Sternal 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 Rib System is composed locking bone plate and locking screws that provide rigid fixation to fractures and osteotomies of the chest wall.
The ARIX Rib 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 bone plates consist of straight type and curved type which has different lengths and number of plate holes. The bone screws are compatible with K181806 ARIX Sternal System Bone Screw previously cleared. The screws are 2.4 and 2.7mm in diameter with self-tapping and provided with lengths from 8.0 to 20.0mm.

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

The ARIX Rib System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies.

7. Technological Characteristics [21 CFR807.92(a)(6)]

Bone Plate: Based on a technical feature comparison, the subject device was found to be similar to all predicate device with regard to design and materials. The subject plates also have a variable locking feature, similar to the design used in the predicate device (K152253).

Bone Screw: They share same head, neck and thread designs as the smaller screws that are previously cleared under the reference device (K181806).

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 results of this testing indicate that the ARIX Sternal 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)(3)]

When compared to the predicate device (K110574), the ARIX Sternal System presented in this submission has similar:

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

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

In all respects, the ARIX Rib System is substantially equivalent to the legally marketed device (K152253). The subject device has similar indication for use, dimension, and technical characteristics as the predicate device. It is therefore concluded that the subject devices are considered substantially equivalent to the predicate devices.