November 26, 2019

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 KR

Re: K192417
Trade/Device Name: ARIX Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 23, 2019
Received: September 4, 2019

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, 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

JEILMEDICAL
702·703·704·705·706·804·805·807·812·815-ho, 55,
Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
Tel : +82 2 850 3533 / Fax : +82 2 850 3536

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)*

K192417

Device Name

ARIX Cannulated Screw System

Indications for Use *(Describe)*

The ARIX Cannulated Screw System is intended for use in internal fixation, reconstruction, or arthrodesis of small bones including the fore, mid-and hind foot and ankle. Also, the ARIX Cannulated Screw System is intended for use in internal fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

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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JEILMEDICAL
702·703·704·705·706·804·805·807·812·815-ho, 55,
Digital-ro 34-gil, Guro-gu, Seoul, 08378, Korea
Tel : +82 2 850 3533 / Fax : +82 2 850 3536

510(k) Summary

[As required by 21 CRF 807.92]

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

25th October, 2019

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 Cannulated Screw System
- Common Name: Bone Screw
- Classification Name: Screw, Fixation, Bone
- Classification Description: Smooth or threaded metallic bone fixation fastener
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3040
- Product Code: HWC
- Device Class: II

JEILMEDICAL
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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	K131311 - ARIX Foot System Jeil Medical Corporation
Additional Predicates	K131566 - ARIX Hand System Jeil Medical Corporation

There are no significant differences between the subject device and the predicate devices (K131311, K131566) 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 Cannulated Screw System consists of cannulated screw with diameters raging from 2.3mm to 6.0mm. The cannulate screws are made of Titanium Alloy(Ti-6Al-4V), ASTM F136, which are widely used for surgical implants with well-known biocompatibility and provided non-sterile. This submission is to reclassify the previously approved device and to add 4.0mm diameter screws.

It also includes washer various manual surgical instruments, such as drill bit, screwdriver shaft, countersink, screwdriver handle, depth gauge, guide pin, cleaning stylet, dispenser, forceps and drill guide.

The ARIX Cannulated Screw 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.

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

The ARIX Cannulated Screw System is intended for use in internal fixation, reconstruction, or arthrodesis of small bones including the fore, mid-and hind foot and ankle. Also, the ARIX Cannulated Screw System is intended for use in internal fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

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

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 device is substantially equivalent to the predicate device in terms of design, indication for use and size scope. (K131311, K131566)

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:

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- ASTM F543, Standard Specification and Test Method for Metallic Medical Bone Screws
  - Driving Torque Test
  - Torsion Test
  - Axial Pull-out Test

The results of this testing indicate that the ARIX Cannulated Screw 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 (K131311), the ARIX Cannulated Screw System presented in this submission has the same:

- 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 Cannulated Screw System is the equivalent of currently marketed devices. This device is made of same materials and has same dimension scope and characteristics. The ARIX Cannulated Screw System is titanium alloy that is used generally in this kind of bone screw. Based on the information submitted, ARIX Cannulated Screw System is substantially equivalent to the currently marketed predicate device.