DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 24, 2017

Jeil Medical Corporation
Yein Han
RA Manager
#702, Kolon Science Valley 2nd
55 Digital-ro 34-gil, Guro-gu
Seoul, 152-728 Korea

Re: K171285
Trade/Device Name: ARIX Diaphysis 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: April 28, 2017
Received: May 1, 2017

Dear Yein Han:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JEIL MEDICAL CORPORATION
702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, 152-728, Korea
Tel : +82 2 850 3934 / Fax : +82 2 850 3536

Indication for Use

510(k) Number (if known): **K171285**

Device Name: ARIX Diaphysis System

Indication for Use:

The ARIX Diaphysis System is intended for intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

Prescription Use ___X___ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JEIL MEDICAL CORPORATION
702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, 152-728, Korea
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510(k) Summary

[As required by 21 CRF 807.92]

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

28th April 2017

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-ho,55 Digital-ro34-gil, Guro-gu, Seoul, 152-728, Korea
- Contact Name: Yein Han / RA Specialist
  - Telephone No. : +82 2 850 3934
  - Fax No. : +82 2 850 3536
  - Email Address : hyi@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 Diaphysis System
- Common Name: Bone Plate and Screw
- Classification Name: Plate, Fixation, Bone / Screw, Fixation, Bone
- Classification Description: Single/multiple component metallic bone fixation appliances and accessories
  Smooth or threaded metallic bone fixation fastener
- Classification Panel: Orthopedic
- Classification Regulation: 21 CFR 888.3030
  21 CFR 888.3040
- 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 Device

- 510(k) Number: K011335
- Device Name: Synthes one-third Tubular DCL Plate

- Additional Predicate Devices

- 510(k) Number: K000684
- Device Name: Synthes Small Fragment Dynamic Compression Locking (DCL) System

- 510(k) Number: K112560
- Device Name: Aptus® Distal Humerus System

- 510(k) Number: K082300
- Device Name: Anatomic Locking Plating System

- Reference Predicate Devices

- 510(k) Number: K112812
- Device Name: LeForte System

- 510(k) Number: K151468
- Device Name: ARIX Wrist System

- 510(k) Number: K131311
- Device Name: ARIX Foot System

- 510(k) Number: K132876
- Device Name: ARIX Locking Hand System

There are no significant differences between the subject devices and the predicate devices (K011335, K000684, K112560, K082300) 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.

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5. Description of the Device [21 CFR 807.92(a)(4)]

The ARIX Diaphysis System is rigid fixation consisting of plates and screws in various configurations, shapes and sizes.

The ARIX Diaphysis 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 lengths and number of plate holes. The screws are self-tapping, which are applied with the reconstruction locking screws together. The Cortical Screws & locking screws are provided with diameter 3.5 mm and lengths from 10 mm to 100 mm.

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

The ARIX Diaphysis System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

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

ARIX Diaphysis 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 (K000684).

ARIX Diaphysis System, Bone Screw:
They share similar head, neck and thread designs as the smaller screws that are currently cleared under the predicate device (K000684).

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

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The following tests were performed with the predicate device:

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

- Screw
  - An engineering analysis was performed to evaluate the torsional strength and pull-out strength of the predicate compared to the subject device screws.

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