DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 21, 2016

Jeil Medical Corporation
Seungyong Lee
RA Specialist
Seoul, 152-728
KOREA

Re: K161746
Trade/Device Name: ARIX Hand 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: August 23, 2016
Received: August 25, 2016

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. 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 Parts 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" (21CFR 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

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Indication for Use

510(k) Number (if known): K161746

Device Name: ARIX Hand System

Indication for Use:

The ARIX Hand 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.

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)

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510(k) Summary

[As required by 21 CRF 807.92]

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

20. June 2016

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, 08378, Korea

- Contact Name: Seungyong Lee / RA Specialist
  - Telephone No. : +82 2 850 3533
  - Fax No. : +82 2 850 3525
  - 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 Hand System
- Common Name: Bone plate & screw
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories
- appliances and accessories
- 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 identified predicate devices within this submission are shown as follow;

- 510(k) Number: K131566
- Applicant: Jeil Medical Corporation
- Common Name: Bone plate & screw
- Device Name: ARIX Hand System

Orthopedic Bone plate & screw
There are no significant differences between the Additional models and the predicate devices (K131566) that would adversely affect the use of the product.

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

The ARIX Hand System is designed to 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. The ARIX Hand System consists of the ARIX Hand System Plate and the ARIX Hand System Screw. The ARIX Hand System Plate is made of Pure Titanium (ASTM F67) and the ARIX Hand System Screw is made of the Titanium Alloy (ASTM F136). This device performance is not adversely affected by aging or storage conditions since this device is to be sterilized at the hospital before use and also to be single use.

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

The ARIX Hand 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)]

ARIX Hand System, Orthopedic: With same thickness and titanium grade. But, the plate and screw changed some dimensions have increased to enhance the strength under the predicate devices (K131566)

Non-Clinical Test Summary:

Bench tests were conducted to verify that the proposed device met all design specifications.

- Plate
  - ASTM F 382-99, Standard Specification and Test Method for Metallic Bone Plates
- Screw
  - ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws

The following tests were performed with the predicate device:

- Plate
  - Tensile strength test
  - Bending strength test per ASTM F382
- Screw
  - Driving torque test per ASTM F543
  - Axial pull-out test per ASTM F543
  - Torsion test per ASTM F543

The results of this testing indicate that the ARIX Hand System is equivalent to predicate device.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

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8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

The subject device has the same device characteristics as the predicate (unmodified) device.
They have the same intended use, raw material, and use concept and employ the same anodization and sterilization method. The differences are in shape and dimensions; however; the performance test data provided in this submission proves the subject device is substantially equivalent to the predicate.

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

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Jeil Medical Corporation concludes that ARIX Hand System Bone Plate & Screw is safe and effective and substantially equivalent to the predicate device as described herein.