DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Jeil Medical Corporation
Sejin Ryu
Regulatory Affairs Specialist, Quality Management Department
702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, Seoul, 152-728
KOREA

January 14, 2016

Re: K151468
Trade/Device Name: ARIX Wrist 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: December 7, 2015
Received: December 10, 2015

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. 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 yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ARIX Wrist System

Indications for Use *(Describe)*
The ARIX Wrist System(Radius) is intended for use in forearm fractures, osteotomies and arthrodesis. The ARIX Wrist System(Ulna) is intended for fractures and osteotomies, in particular for the ulna.

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)]

14 January, 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, 152-728, Korea
- Contact Name: Sejin RYU (Ms.) / RA Specialist
  - Telephone No. : +82 2 850 3500
  - Fax No. : +82 2 850 3525
  - 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 Wrist System
- Common Name: Bone plates and screws
- Classification Name: Single/multiple component metallic bone fixation appliances and accessories
- 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;

- 510(k) Number: K103332
- Applicant: Medartis AG
- Common Name: plate, fixation, bone
- Device Name: APTUS® Ulna Plates

- 510(k) Number: K142906
- Applicant: Medartis
- Common Name: Plate, fixation, bone
  Screw, Fixation, Bone
- Device Name: APTUS® Wrist 2.5 System

There are no significant differences between the Model ARIX Wrist System 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 Wrist System is consists of the Radius & Ulna. It is rigid fixation plates and screws which were recommended combination as follow;

Type / Configuration	Plate	Screw	
		Self-tapping Cortical Screw	Self-tapping Locking Screw
Radius	25-DVRA Series	25-HF Series	161.0325 Series
Ulna	25-DLUL Series	25-HF Series	25L-HF Series
Material	ASTM F 67 Pure Titanium	ASTM F 136 Titanium Alloy (Ti-6Al-4V)	ASTM F 136 Titanium Alloy (Ti-6Al-4V)

The ARIX Wrist System is made of Pure 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 h are widely used for surgical implants with well-known biocompatibility. The plates vary essentially through different lengths and number of plate holes. The self-tapping cortical screws & self-tapping locking screws diameter is 2.5mm and lengths is from 8mm to 38mm. It also includes various manual surgical instruments, as drill guides, drill bits, driver shafts, depth gauge, bender and

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handbody etc,. The ARIX Wrist 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.

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

The ARIX Wrist System(Radius) is intended for use in forearm fractures, osteotomies and arthrodesis. The ARIX Wrist System(Ulna) is intended for fractures and osteotomies, in particular for the ulna.

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

ARIX Wrist System, Bone Plates: 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 poly axial locking feature, similar to the design used in the predicate devices (K103332/ K142906).

ARIX Wrist System, Bone Screws: They share similar head, neck and thread designs as the smaller screws that are currently cleared under the predicate devices (K142906).

Non-Clinical Test Summary:

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

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

The following tests were performed with the predicate devices:

- Plates
  - Dimension test
  - Single Cycle Bending test per ASTM F382
  - Bending Fatigue test per ASTM F382
- Screws
  - Dimension test
  - Driving torque test per ASTM F543-07
  - Axial pull-out test per ASTM F543-07
  - Torsion test per ASTM F543-07

The results of this testing indicate that the ARIX Wrist System is equivalent to predicate devices.

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]

When compared to the predicate devices (K103332/ K142906), the ARIX Wrist System presented in this submission has the same;

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biocompatibility
- Materials
- Method of sterilization and sterility assurance level

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

In all the respects, the ARIX Wrist System is the equivalent of currently marketed devices. This device is made of the same materials and has similar dimensions and characteristics. This device is manufactured from material of the Pure Titanium and Titanium Alloy, Unalloyed titanium and Wrought titanium alloy that is used generally in this kind of bone plate/screw system. This device, ARIX Wrist System, is substantially equivalent in design, material, and function to the predicate devices.