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

May 2, 2017

Beijing Keyi Medical Device Technology Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CN

Re: K162380
Trade/Device Name: Locking Plate 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 1, 2017
Received: April 3, 2017

Dear Ms. Diana Hong:

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

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)*
K162380

Device Name
Locking Plate System

Indications for Use *(Describe)*
Locking Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur, tibia and fibula.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K162380

1. Date of Preparation: 04/25/2017

2. Sponsor Identification

Beijing KeYi Medical Device Technology Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Jing Cheng (Alternative Contact Person)

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Fax: 240-238-7587
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4. Identification of Proposed Device

Trade Name: Locking Plate System
Common Name: Metallic Bone Plates and Bone Screws

Regulatory Information

Plate
Classification Name: Plate, Fixation, Bone
Classification: II
Product Code: HRS
Regulation Number: 21 CFR part 888.3030
Review Panel: Orthopedic

Screw
Classification Name: Screw, Fixation, Bone
Classification: II
Product Code: HWC
Regulation Number: 21 CFR part 888.3040
Review Panel: Orthopedic

Indications for Use:

Locking Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur, tibia and fibula.

Device Description

The proposed product, Locking Plate System, contains (1) Locking Plates, (2) Locking screws and (3) various specific instruments.

The raw material of the plate, titanium, conforms to ASTM F67-13, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNSR50550, UNS R50700). The bone screws are made of titanium alloy (TI-6AL-4V ELI), which complies with ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

The devices are provided un-sterilized, but shall be sterilized via autoclave method to achieve Sterility Assurance Level of 10^{-6} by hospital prior to use.

5. Identification of Predicate Devices

Primary Predicate
510(k) Number: K101400
Product Name: Locking Compression Plate
Manufacturer: Changzhou Orthmed Medical Instrument Co., Ltd.

Additional Predicate
510(k) Number: K100721
Product Name: Locking Bone Screw
Manufacturer: Changzhou Orthmed Medical Instrument Co., Ltd.

Additional Predicate
510(k) Number: K130340
Product Name: Locking Bone Plates and Screws
Manufacturer: Weigao Orthopaedic Device Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates
- ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws
- ASTM F67-13, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNSR50550, UNS R50700).
- ASTM F136-13: Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNSR56401).
- ASTM F138-13, Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).
- 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.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM		**Proposed Device** Locking Plate System	**Primary Predicate,K101400** Locking Compression Plate
Product Code		Plate: HRS	Plate: HRS
		Screw: HWC	N.A.
Regulation No.		Plate: 21 CFR 888.3030	Plate: 21 CFR 888.3030
		Screw: 21 CFR 888.3040	N.A.
Class		Class II	Class II
Intended Use		Locking Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur, tibia and fibula.	Locking Compression Plate can be used for adult patients with age above 21 as indicated for fixation of features, including ulna,radius, humerus, femur and tibia.
Features of Locking Plates		Slots-Limited Contact Area	Slots-Limited Contact Area
		Combi-Holes	Combi-Holes
Features of Locking Screws		Self-tapping locking screws and Self-tapping-drilling locking screws	N.A.
Material		Locking Plates: Titanium	Locking Plate: Titanium alloy
		Locking Screws: Titanium alloy	N.A.
How supplied		Non-Sterile, Subject to steam sterilized prior to use.	Non-Sterile, Subject to steam sterilized prior to use.
Performance	Plate	Static and Dynamic Performance were tested per ASTM F 382	Static and Dynamic Performance were tested per ASTM F 382
	Locking screw	Torsional, Driving Torque and Pull- out Strength performance were tested per ASTM F543	Torsional, Driving Torque, Pull- out strength performance was evaluated per ASTM F543 for screws cleared in K100721

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.