



Food and Drug Administration
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Tianjin Zhengtian Medical Instrument Co., Ltd
Yifan Fu
Regulatory Affairs Specialist
No.318, Jingyi Road, Airport Economic Zone
Tianjin, 300308
CHINA

February 25, 2016

Re: K151508

Trade/Device Name: IRENE Locking Compression 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: January 8, 2016

Received: January 13, 2016

Dear Yifan Fu:

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 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)

K151508

Device Name

IRENE Locking Compression Plate System

Indications for Use (Describe)

The IRENE Locking Compression Plate System is indicated for patients with age above 21 for fixation of fractures. Indicated fracture areas include ulna, radius, humerus, femur, and tibia.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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IRENE

Section 10 510(k) Summary

This document is prepared to provide sufficient information for an understanding of the basis for the determination of substantial equivalence, as required by 21 CFR section 807.92(c).

1. 510(k) Submitter and Owner

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Date of Preparation of the Summary: Feb 25th, 2016

2. Submission Contact

Fu, Yifan

Position: Regulatory Affairs Specialist

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3. Proposed Device

Trade name - IRENE Locking Compression Plate System

Common name - Locking compression plate and screw

Class: Class 2

Regulation -21 CFR 888.3030, Product Code HRS (Bone Fixation Plate)

-21 CFR 888.3040, Product Code HWC (Bone Fixation Screw)

Review Panel: Orthopedic

The IRENE Locking Compression Plate System is designed for internal fixation of bones that subject to fracture. The system includes bone plates and screws that can be used with the plate. Various sizes of plate are available for different fracture areas or clinical conditions. Bone screws are incorporated in the system and are intended to fix with plate with appropriate size. The plate has a limited-contact design. The plate system is provided unsterile. And the system is intended for

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single-use.

Indications for Use:

The IRENE Locking Compression Plate System is indicated for patients with age above 21 for fixation of fractures. Indicated fracture areas include ulna, radius, humerus, femur, and tibia.

4. Predicate Device

	Predicate Device 1	Predicate Device 2	Predicate Device 3
510(k) Number	K101400	K100721	K112819
Predicate Device Name	Locking Bone Plate	Locking Bone Screw	3.5mm Locking Screw
Manufacturer	Changzhou Orthmed Medical Instrument Co., Ltd.		Xiamen Double Engine Medical Material Co., Ltd.
Classification	888.3030(HRS)	888.3040(HWC)	888.3040(HWC)

5. Preclinical Data

Mechanical testing is conducted to demonstrate differences in technological characteristics of the proposed device to predicate device do not raise new question regarding safety and effectiveness, and Substantially Equivalent to the predicate device is thus concluded. The testing incorporates the following standards as test method to evaluate the performance of both proposed and predicate device:

- 1) ASTM F 382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates.
- 2) ASTM F543-13, Standard Specification and Test Methods for Metallic Medical Bone Screws.

6. Clinical Data

No clinical data is presented in this submission.

7. Substantial Equivalence Comparison



Element	Proposed Device IRENE Plate and Screw	Predicate Device Orthmed Plate and Screw	Predicate Device Double Engine 3.5mm Locking Screw
Class	2	2	2
Regulation number	Plate: 21 CFR 888.3030	Plate: 21 CFR 888.3030	Not referenced
	Screw: 21 CFR 888.3040	Screw: 21 CFR 888.3040	Screw: 21 CFR 888.3040
Intended use	Internal fixation of bone fractures	Internal fixation of bone fractures	Internal fixation of bone fractures
Design	Plate: straight, tubular cross-section, locking compression screw hole, has limited contact area.	Plate: straight, tubular cross- section, locking compression screw hole, has limited contact area. Dimensions and contour has slight difference.	Not referenced
	Screw: self-tapping, fully threaded locking screw.	Screw: self-tapping, fully threaded locking screw. The contour has very slight difference.	Screw: 3.5mm diameter, self- tapping locking screw.
Material	Plate: titanium	Plate: titanium alloy	Not referenced
	Screw: titanium alloy	Screw: titanium alloy	Screw: titanium alloy
How Supplied	Non-sterile	Non-sterile	Non-Sterile
Single-Use Only	Yes	Yes	Yes
Sterilization	Moist heat sterilization prior to use	Moist heat sterilization prior to use	Moist heat sterilization prior to use
Performance data	Plate: static and dynamic testing conducted as per ASTM F382-13	Plate: static and dynamic testing conducted as per ASTM F382-13	Not referenced
	Screw: torsional	Screw: torsional	Screw:

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 IRENE

	properties, driving torque and pull-out strength are conducted as per ASTM F543-13	properties, driving torque and pull-out strength are conducted as per ASTM F543-13	performance testing conducted as per ASTM F543-07
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The proposed device is found to possess highly similar technological characteristics on design under the premises of sharing same intended use. Device performance is compared through the testing of mechanical properties of the proposed and predicate device by methods stipulated in published standards in order to evaluate whether differences existing in the design raise safety issue by compromising performance. Results of testing indicates no gap between the level of performance of proposed device and the predicate device, through which the differences are deemed not relevant to device performance and has been justified, and the conclusion of Substantial Equivalence is reached.