

K131759

AUG 8 2013

Premarket Notification 510(k) Submission

Section 3 510k Summary

Project #: M0152013Ad

Section 3 510(k) Summary

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

The assigned 510(k) Number: _____

3.1 Date of Submission

06/07/2013

3.2 Sponsor Identification

Tianjin Walkman Biomaterial Co., Ltd
No.19, Technology Road, Tianjin Tianyu Science and Technology Garden
Jinghai East, Tianjin, P.R. China 301609

Establishment Registration Number: Not yet registered

Contact Person: Ms. Fengmei Ren
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3.3 Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
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3.4 Proposed Devices Identification

Proposed Device Name: Metallic Locking Bone Plates and Metallic Locking Bone Screws

Regulatory Information of Plates:

Classification Name: Plate, Fixation, Bone

Common Name: Bone Plates

Class: Class II

Product Code: HRS

Regulation Number: 21 CFR 888.3030

Review Panel: Orthopedic

Regulatory Information of Screws:

Classification Name: Screw, Fixation, Bone

Common Name: Bone Screws

Class: Class II

Product Code: HWC

Regulation Number: 21 CFR 888.3040

Review Panel: Orthopedic

Intended Use Statement:

Metallic Locking Compression Bone Plates and Screws System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.

3.5 Device Description

Metallic Locking Compression Bone Plates and Screws System contains (1) locking compression plates (LCPs) with various specifications, (2) two kinds of screws with various specifications and (3) various specific instruments. Locking Compression Plates are the plates that made of Titanium. They have combi-holes. the threaded hole sections on the plates for locking screws provides ability to create fixed-angle constructs; the un-threaded hole sections for cortex screws allows utilization of familiar AO plating techniques. The limited-contact design of LCPs reduces plate-to-bone contact, thus limiting vascular trauma. The screws are available in locking screws and cortex screws. There are various instruments specific to the proposed device intend for completing the surgery.

3.6 Predicate Device Identification

Predicate Device 1

510(k) Number
K101400

Predicate Device Name
Locking Compression Plate

Manufacturer
Changzhou Orthmed Medical Instrument Co., Ltd

Predicate Device 2

510(k) Number
K100721

Predicate Device Name
Locking Bone Screw

Manufacturer
Changzhou Orthmed Medical Instrument Co., Ltd

Predicate Device 3

510(k) Number
K073159

Predicate Device Name
Trauson Bone Screw

Manufacturer
Trauson (Jiangsu) Medical Instrument Co., Ltd

3.7 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:

- a) ASTM F382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates.
- b) ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws.

3.8 Clinical Testing Conclusion

No clinical study is included in this submission.

3.9 Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
Product Code	HRS	HRS	/	/
	HWC	/	HWC	HWC
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	/	/
	21 CFR 888.3040	/	21 CFR 888.3040	21 CFR 888.3040
Intended Use	Metallic Locking Compression Bone Plate and Screw System is intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.	Locking Compression Plate can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.	Locking Bone Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.	Trauson Bone Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.
Material	Plate: Titanium	Plate: Titanium	/	/
	Cortex Screw: Titanium alloy	/	/	Cortex Screw: Stainless Steel
	Locking Screw:	/	Locking Screw:	/

	Titanium alloy		Titanium alloy	
How supplied	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Single Use	Yes	Yes	Yes	Yes
Sterile	Subject to steam sterilized prior to use.	Subject to steam sterilized prior to use.	Subject to steam sterilized prior to use.	Subject to steam sterilized prior to use.
Performance	Static and Dynamic Performance tested per ASTM F382 Torsional, Driving Torque and Pull out strength tested per ASTM F543.	Static and Dynamic Performance tested per ASTM F382	Torsional, Driving Torque and Pull out strength tested per ASTM F543.	Torsional, Driving Torque and Pull out strength tested per ASTM F543.

Differences in intended use, material and performance between the proposed and predicate device have been discussed and address. The proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, in respect of safety and effectiveness.



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

August 8, 2013

Tianjin Walkman Biomaterial Company, Limited
% Mid-Link Consulting Company, Limited
Ms. Diana Hong
General Manager
PO Box 120-119
Shanghai, 200120, China

Re: K131759

Trade/Device Name: Metallic Locking Compression Bone Plates and Screws System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 19, 2013
Received: July 22, 2013

Dear Ms. 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

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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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith

For

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

Enclosure

