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

Changzhou Waston Medical Appliance Company, Limited
% Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai, 200120
CHINA

December 17, 2015

Re: K151062
Trade/Device Name: WASTON Metallic Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 30, 2015
Received: November 3, 2015

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 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)* K151062

Device Name
WASTON Metallic Intramedullary Nail System

Indications for Use *(Describe)*
•Simple, compound first- and second-degree tibial shaft fractures
•Pseudarthrosis and delayed union

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.

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Tab #7 510(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: K151062

1. Date of Preparation: 01/13/2015

2. Sponsor Identification

CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD.
9 Xihu Road, Wujin Hi-tech Industry Zone, Changzhou, Jiangsu, 213168, China

Establishment Registration Number: Not yet registered

Contact Person: Mr. Jack Lu
Position: International Department Director
Tel: +86-519-86522226
Fax: +86-519-86221108
Email: Waston18@gmail.com

3. Designated Submission Correspondent

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

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: WASTON Metallic Intramedullary Nail System
Common Name: Intramedullary nail

Regulatory Information

Classification Name: rod, fixation, intramedullary and accessories;
Classification: II
Product Code: HSB
Regulation Number: 21 CFR 888.3020
Review Panel: Orthopedic

Intended Use Statement:

- Simple, compound first- and second-degree tibial shaft fractures
- Pseudarthrosis and delayed union

Device Description

The WASTON Metallic Intramedullary Nail System is a temporary fixation intramedullary nail designed for fracture fixation and stabilization of the tibia. The system consists of intramedullary nail, locking screw, end cap and instruments.

The intramedullary nail is available in a variety of lengths to meet assorted anatomical needs. Each of the nails is secured by a series of screws that pass through holes manufactured into the proximal and distal sections.

All implants of Metallic Intramedullary Nail System are manufactured from Ti-6Al-4V alloy that meets the requirements of ASTM F-136.

The proposed 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 Device

510(k) Number: K132078
Product Name: Metallic Intramedullary Nail System

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 F1264-03 (Reapproved 2012): Standard specification and test methods for intramedullary fixation devices.
- ASTM F543-13: Standard specification and test method for metallic medical bone screws.
- 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(s)	Predicate Device K132078
Product Code		HSB	Same
Regulation Number		21 CFR 888.3020	Same
Intended Use		·Simple, compound first- and second-degree tibial shaft fractures ·Pseudarthrosis and delayed union	Same
Configuration		Nail, Screw and End Cap	Same
Sterile		The devices are supplied non-sterile, it should be sterilized prior to use by professional and the sterilization should achieve SAL 1×10^{-6}	Same
Single Use		Yes	Same
Material		Titanium Alloy (TI -6A1-4 V ELI)	Same
Physical Specification	Nail	Proximal/Distal diameter: φ10/φ8 mm, φ10/φ9 mm, φ10/φ10 mm; Length: 240~340 mm	Same
	Screw	Diameter: φ6mm Length: 20~95 mm	Similar
Mechanical Specification	Nail	Static bending, Dynamic bending and Static Torsional performance were tested per ASTM F1264	Same
	Screw	Dynamic bending performance was tested per ASTM F1264; Driving torque and pull-out performance were tested per ASTM F543	Same

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 device.