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

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

August 10, 2015

Re: K151057
Trade/Device Name: WASTON Metallic Bone Plate and Screw Systems
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: June 23, 2015
Received: July 6, 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 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" (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)*
K151057

Device Name
WASTON Metallic Bone Plate and Screw Systems

Indications for Use *(Describe)*
WASTON Metallic Bone Plate and Screw Systems are intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, nonunions and malunions, and osteotomies of the femur.

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.

Exhibit 2 # 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: K151057

1. Date of Preparation: 06/17/2015

2. Sponsor Identification

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

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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 Bone Plate and Screw Systems
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

Intended Use Statement:

WASTON Metallic Bone Plate and Screw Systems are intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, nonunions and malunions, and osteotomies of the femur.

Device Description

The proposed products, WASTON Metallic Bone Plate and Screw Systems, contain (1) Distal lateral femoral (condylar) LOC plate, (2) Bone 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

Predicate device 1
510(k) Number: K062564
Product Name: Synthes LCP Distal Femur Plates
Manufacturer: Synthes (USA)

Predicate device 2
510(k) Number: K000682
Product Name: Synthes Large Fragment Dynamic Compression Locking System (DCL) (5.0 Locking Screws)
Manufacturer: Synthes (USA)

Predicate device 3
510(k) Number: K112583
Product Name: Synthes Cortical Screws (4.5 Cortex Screws)
Manufacturer: Synthes (USA)

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 proposed device complies with the following standards:

- 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.

The proposed bone plate and predicate bone plate were tested together per the following standard, to evaluate the performance of the proposed bone plate and predicate bone plate. The test results demonstrated that the mechanical performance of proposed device is similar or better as the predicate, and supported a determination of substantial equivalence between the proposed device and predicate device.

- ASTM F382-99 (Reapproved 2008), Standard Specification and Test Method for Metallic Bone Plates, including the following items:
  Static four-point bending test
  Dynamic four-point bending test

The proposed bones screw and predicate screws were tested together per the following standard, to evaluate the performance of the proposed bone screws and predicate bone screws. The test results demonstrated that the mechanical performance of proposed device is similar or better as the predicate, and supported a determination of substantial equivalence between the proposed device and predicate device.

- ASTM F543-13, Standard Specification and Test Methods for Metallic Medical Bone Screws, including the following items:
  Torsional properties
  Driving torque
  Pull-out test
  Self-tapping test

7. Clinical Test Conclusion

No clinical study is included in this submission.