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
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai, 200120
CHINA

November 18, 2015

Re: K150684
Trade/Device Name: WASTON General Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: October 21, 2015
Received: October 23, 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" (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 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)*
K150684

Device Name
WASTON General Spinal System

Indications for Use *(Describe)*
The WASTON General Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion, (5) pseudarthrosis, (6) spinal stenosis. It is not intended for pedicle screw fixation above T8.

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: K150684

1. Date of Preparation: 08/27/2014

2. Sponsor Identification

CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD
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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: WASTON General Spinal System
Common Name: General Spinal System

Regulatory Information

Classification Name: Pedicle screw spinal system
Classification: II
Product Code: MNI, MNH
Regulation Number: 21 CFR part 888.3070
Review Panel: Orthopedic

Intended Use Statement:

The WASTON General Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion, (5) pseudarthrosis, (6) spinal stenosis. It is not intended for pedicle screw fixation above T8.

Device Description

The WASTON General Spinal System consists of Fixed-Angle Screws, Fixed-Angle Reduction Screws, Rods, Crosslink and Set Screws. The proposed general spinal system is made of Titanium Alloy (Ti6Al4VELI), which meets ASTM F136-02a, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility

The proposed devices are provided non-sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The recommended sterilization method was validated per 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.

5. Identification of Predicate Device(s)

510(k) Number: K082617
Product Name: Trauson General Spinal System (GSS)
Model Name: GSS-II

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 F1717-14, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model including the following items:

- Static compression bending test;
- Dynamic compression bending test;
- Static torsion test.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics (Scalpel System)

Item	Proposed Device(s)	Predicate Device(s) K082617
Product Code	MNH	MNH
	MNI	MNI
Regulation Number	21 CFR 888.3070	21 CFR 888.3070
Intended Use	The WSTON General Spinal System is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities deformities: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion, (5) pseudarthrosis, (6) spinal stenosis. It is not intended for pedicle screw fixation above T8.	Trauson General Spinal System (GSS) is intended for posterior pedicle screw fixation (GSS-VII can be applied for anterior or anterolateral fixation) of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities deformities. When used as a posterior spine thoracic/lumbar system, Trauson General Spinal System (GSS) is indicated for one or more of the following: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion, (5) pseudarthrosis, (6) spinal stenosis. Trauson General Spinal (GSS) is not intended for pedicle screw fixation above T8.
Configurations	Rod	Rod
	Fixed-Angle Screw	N.A.
	Fixed-Angle Reduction Screws	Fixed-Angle Reduction Screws
	Set Screws	Set Screws
Material	Titanium alloy	Titanium alloy
Sterile	Subject to steam sterilized prior to use.	Subject to steam sterilized prior to use.
Single Use	Yes	Yes
Performance	ASTM F 1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	ASTM F 1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

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.