



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Shandong Weigao Orthopaedic Device Company, Ltd
% Ms. Diana Hong
General Manager
Mid-link Consulting Company, Ltd
P.O. Box 120-119
Shanghai 200120
CHINA

April 1, 2016

Re: K160320
Trade/Device Name: Premier
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: February 1, 2016
Received: February 5, 2016

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

Indications for Use

510(k) Number (if known)

K160320

Device Name

Premier

Indications for Use (Describe)

The Premier is intended for posterior, non-cervical, pedicle fixation for the following indications: severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K160320

1. Date of Preparation: 03/24/2016

2. Sponsor Identification

Shandong Weigao Orthopaedic Device Co., Ltd.

No. 26 Xiangjiang Road, Tourist Resorts Weihai Shandong 264203 China

Establishment Registration Number: 3006639944

Contact Person: Han Wang

Position: R&D Vice Director

Tel: +86-631- 5788966

Fax: +86-631-5660958

Email: wanghan@wegortho.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

Ms. Ying Xu (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: Premier

Common Name: General Spinal System

Regulatory Information

Primary Classification Name: Pedicle screw spinal system

Primary Regulation Number: 21CFR 888.3070

Classification: II

Product Codes: MNI, MNH

Review Panel: Orthopedic

Subsequent Classification Name: Spinal interlaminar fixation orthosis

Subsequent Regulation Number: 21CFR 888.3050

Classification: II

Product Code: KWP

Review Panel: Orthopedic

Intended Use Statement:

The Premier is intended for posterior, non-cervical, pedicle fixation for the following indications: severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae; trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft.

Device Description

The premier consists of fixed-angle screws, fix-angle reduction screws, multi-axial screws, multi-axial reduction screws, rods, crosslink plates, set screws, planar screw, iliac screw, domino connector, lateral connector and hooks

It is made of Titanium Alloy (Ti6Al4V), which meets ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium (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 Primary Predicate Device

510(k) Number: K113666

Product Name: XIA®3 Spinal System

6. Non-Clinical Test Conclusion

Non clinical tests and engineering rationales 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 F 1717-13, 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

Item	Proposed Device	Predicate Device K113666
Product Code	MNI, MNH, KWP	OSH, MNH, MNI, KWP, NKB
Regulation Number	21 CFR part 888.3070, 21 CFR part 888.3050	21 CFR part 888.3070, 21 CFR part 888.3050
Intended Use	The Premier is intended for posterior, non-cervical, pedicle fixation for the following indications:	The XIA®3 Spinal System is intended for use in the noncervical spine. When used an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA®3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally

		mature patient in the treatment of the following acute and chronic instabilities or deformities
	Severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae	Spondylolisthesis
	Trauma (i.e. fracture or dislocation)	Trauma
	Spinal stenosis	Spinal stenosis
	Curvatures (i.e. scoliosis, kyphosis, and/or lordosis);	Curvatures (i.e. Scoliosis, kyphosis, and/or lordosis)
	Tumor	Tumor
	Pseudoarthrosis;	Pseudoarthrosis
	Failed previous fusion.	Failed previous fusion
	The device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft.	Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
Configuration	Rod	Rod
	Multi Axial Screw	Multi Axial Screw
	Multi-Axial Reduction Screw	NA
	Fixed Angle Screw	Fixed Angle Screw
	Fixed Angle Reduction Screw	NA
	Planar Screw	Planar Screw
	Iliac Screw	Iliac Screw
	Crosslink Plate	Crosslink Plate
	Set Screw	Blocker
	Domino Connector	Domino Connector
	Lateral Connector	Lateral Connector
Sterile	Hook	Hook
	Steam	Steam
	10 ⁻⁶	10 ⁻⁶

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.