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

Shandong Weigao Orthopaedic Device Co., Ltd. August 4, 2017
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K170861
Trade/Device Name: Premier
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: July 5, 2017
Received: July 6, 2017

Dear Mr. Eggleton:

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" (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,

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)*
K170861

Device Name
Premier

Indications for Use *(Describe)*
The Premier is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1-S1): degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; and failed previous fusion (pseudoarthrosis).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
PRAStaff@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."

510(k) Summary

Device Trade Name:	Premier
Manufacturer:	Shandong Weigao Orthopaedic Device Co., Ltd. No. 26 Xiangjiang Road, Tourist Resorts Weihai, Shandong China 264203 +86-631-5788966
Contact:	Han Wang R&D Vice Director Shandong Weigao Orthopaedic Device Co., Ltd. No. 26 Xiangjiang Road, Tourist Resorts Weihai, Shandong China 264203
Prepared by:	Mr. Justin Eggleton Senior Director, Spine Regulatory Affairs Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: (202) 552-5800 jeggleton@mcra.com
Date Prepared:	July 5, 2017
Classification:	21 CFR §888.3070, Thoracolumbosacral pedicle screw system
Class:	II
Product Codes:	NKB, KWP
Predicate Device:	Weigao Orthopaedic Premier (K160320)
Additional Predicate Devices:	EXPEDIUM® Spine System (K101070) Vitality® Spinal Fixation System (K150896)

Indications for Use:
The Premier is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1-S1): degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; and failed previous fusion (pseudoarthrosis).

Device Description:
The purpose of this 510(k) is to make modifications to the previously cleared Premier Spinal System (K160320). The changes include modifications to the implants, surgical instruments, indications and labeling. 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.

Predicate Device:
The subject Premier is substantially equivalent to the primary predicate device Premier (K160320) and additional predicate devices EXPEDIUM® Spine System (K101070) and Vitality® Spinal Fixation System (K150896) with respect to indications, design, materials, function, and performance.

Performance Testing:
The performance of the subject Premier System was determined based on a series of engineering rationales compared to the predicate devices cited in the previous section

Substantial Equivalence:
The subject Premier System is substantially equivalent to the primary predicate device Premier (K160320) and additional predicate devices EXPEDIUM® Spine System (K101070) and Vitality® Spinal Fixation System (K150896) with respect to indications, design, materials, function, and performance.