



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

Beijing Weigao Yahua Artificial Joint Development Company, Limited
% Ms. Diana Hong
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai 200120
CHINA

February 1, 2016

Re: K152324

Trade/Device Name: YAHUA Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: January 6, 2016
Received: January 11, 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 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 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)

K152324

Device Name

YAHUA Spinal System

Indications for Use (Describe)

The YAHUA Spinal System 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. The levels of fixation are T8 – S1.

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.”

510(k) Summary

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

1. Date of Preparation: 06/20/2015
2. Sponsor Identification

Beijing Weigao Yahua Artificial Joint Development Co. Ltd.

No.7, NiuHui Street, NiuLanShan Town ,ShunYi District ,Beijing, 101301, China

Establishment Registration Number: Not yet registered

Contact Person: Xinjian Lv

Position: R&D Manager

Tel: +86-10-69416956

Fax: +86-10-69416956

Email: lxj@wegojoint.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

Mr. Lee Fu (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: YAHUA Spinal System

Regulatory Information

Classification Name: Pedicle screw spinal system

Classification: Class II

Product Code: MNI, MNH, KWP

Regulation Number: 21 CFR part 888.3070, 21 CFR part 888.3050

Review Panel: Orthopedic

Indications for Use:

The YAHUA Spinal System 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. The levels of fixation are T8 – S1.

Device Description

The spinal system consists of screws, rods, crosslink plates, set screws and hooks.

It 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. Primary Predicate

510(k) Number: K122994

Product Name: General Spinal System

Manufacturer: Weigao Orthopaedic Device Co., Ltd

6. Non-Clinical Test Conclusion

The proposed device and predicate device are tested together per the following standard, to evaluate the performance of the proposed device and the predicate device. The test results demonstrated that the mechanical performance of proposed device is similar as the predicate.

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

Item	Proposed Device YAHUA Spinal System		Predicate Device General Spinal System K122994
Product Code	MNI, MNH, KWP		MNI, MNH, KWP
Regulation Number	888.3070 and 888.3050		888.3070 and 888.3050
Intended Use	The YAHUA Spinal System is intended for posterior, non-cervical, pedicle fixation for the following indications:		The General Spinal System is intended for posterior, non-cervical, pedicle fixation for the following indications:
	Severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae		Severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebrae
	Trauma (i.e. fracture or dislocation)		Trauma (i.e. fracture or dislocation)
	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
Configuration	Rods		Rods
	Multi Axial Screws		Multi Axial Screws
	Multi-Axial Reduction Screws		Multi-Axial Reduction Screws
	Fixed Angle Screw		Fixed Angle Screw
	Fixed Angle Reduction Screws		Fixed Angle Reduction Screws
	Crosslink Plate		Crosslink Plate
	Set Screws (Non Break-off, Break-off)		Set Screws (Non Break-off, Break-off)
Sterile	Provided Non-Sterile, required to be sterilized prior to operation.		Provided Non-Sterile, required to be sterilized prior to operation.
	Method: Steam		Method: Steam
	SAL: 10 ⁻⁶		SAL: 10 ⁻⁶
Single Use	Yes		Yes
Material	Implant	Titanium Alloy (Ti-6Al-4V ELI) Conforms to ASTM F136	Titanium Alloy (Ti-6Al-4V ELI) Conforms to ASTM F136

	instruments	Stainless Steel Conforms to ASTM F138	Stainless Steel Conforms to ASTM F138
--	-------------	--	--

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.