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

May 5, 2016

Hung Chun Bio-S Company, Limited
% Mr. Michael Lee
Acmebiotechs Consulting Incorporation
38F-7, No. 368, Sec. 1, Wenhua Road, Banqiao District
New Taipei City 22041
TAIWAN (R.O.C.)

Re: K151362
Trade/Device Name: HC Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: April 15, 2015
Received: April 20, 2016

Dear Mr. Lee:

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)*
K151362

Device Name
HC Spinal System

Indications for Use *(Describe)*
The HC Spinal System is intended for posterior noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients for the following indications: severe spondylolisthesis (i.e., Grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

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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"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

1	**Type of Submission:**	Traditional
2	**Date of Summary:**	April 15, 2016
3	**Submitter:**	Hung Chun Bio-S Co., Ltd.
	Address:	No.12, Luke 1st Rd., Luzhu Dist. Kaohsiung City 821, Taiwan (R.O.C.)
	Phone:	+886-7-695-5369
	Fax:	+886-7-695-5379
	Contact:	Hsin Tai Hu (tai@hc-bios.com)

4 Identification of the Device:

Proprietary/Trade name:	HC Spinal System
Device Classification:	II
Panel:	Orthopedic
Regulation Number:	888.3070
Product Code:	MNH, MNI
Classification Name:	Pedicle screw spinal system

5 Identification of the Predicate Device:

Predicate Device Name:	Xia® 4.5 Spinal System
Manufacturer:	Stryker Spine
Regulation number:	888.3070, 888.3050, 888.3060
Product Code:	MNH, MNI, KWP, KWQ
510(k) Number:	K050461

6 Intended Use and Indications for Use of the subject device

The HC Spinal System is intended for posterior noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients for the following indications: severe spondylolisthesis (i.e., Grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

7 Device Description

The HC Spinal System offers a comprehensive solution for immobilizing and stabilizing spinal deformities in patients as an adjunct to fusion. The HC Spinal System consists of monoaxial and polyaxial pedicle screws, set screw and rods. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy. The implants will be provided non-sterile and will be used for either posterior or anterolateral non cervical fixation.

8 Non-clinical Testing

A series of tests were performed on the proposed device, HC Spinal System.

- Shelf Life Test
- *In vitro* Cytotoxicity Test
- Intracutaneous Irritation Study
- Skin Sensitization Study
- Pyrogen Test
- Acute Intravenous Systemic Toxicity Study
- Acute Intraperitoneal Systemic Toxicity Study
- *Salmonella* Reverse Mutation Test
- *In Vitro* Mammalian Chromosomal Aberration Test
- Rodent Micronucleus Test
- Bone Implantation Study

- Subchronic Intravenous Systemic Toxicity Study
- Static and Dynamic axial Compress Bending Testing
- Static Torsional Test

All the test results demonstrate that HC Spinal system meets the requirements of its pre-defined acceptance criteria and intended uses.

9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

10 Substantial Equivalence Determination

The HC Spinal system submitted in this 510(k) file is substantially equivalent in intended use, technology/principles of operation, materials and performance to the cleared Xia® 4.5 Spinal System. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

	Proposed Device	Predicate Device
Item	HC Spinal System	Xia® 4.5 Spinal System (K050461)
Classification	Class II	Class II
Product Code	MNH, MNI	MNH, MNI, KWP, KWQ
Intended Use	The HC Spinal System is intended for posterior noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients for the following indications: severe spondylolisthesis (i.e. Grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic	The XIA® 4.5 Spinal System is intended for posterior noncervical pedicle fixation for the following indications: severe spondylolisthesis (i.e. Grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e. fracture or

<table>
<tr><td></td><td>impairment), trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.</td><td>dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.
The XIA® 4.5 Spinal System is also intended for anterolateral and posterior, non-cervical, non-pedicle fixation for the following indications: 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, pseudoarthrosis and failed previous fusion.</td></tr>
<tr><td>Material</td><td>Titanium Alloy</td><td>Titanium Alloy</td></tr>
<tr><td>Material Compliance</td><td>ASTM F136</td><td>ASTM F136</td></tr>
<tr><td>Monoaxial Screws</td><td>
<table>
<tr><th>Diameter (mm)</th><th>Length (mm)</th></tr>
<tr><td>Ø 4.5</td><td>30, 35, 40, 45, 50, 55, 60</td></tr>
<tr><td>Ø 5.0</td><td>30, 35, 40, 45, 50, 55, 60</td></tr>
<tr><td>Ø 5.5</td><td>30, 35, 40, 45, 50, 55, 60</td></tr>
<tr><td>Ø 6.0</td><td>30, 35, 40, 45, 50, 55, 60</td></tr>
<tr><td>Ø 6.5</td><td>30, 35, 40, 45, 50, 55, 60</td></tr>
</table>
</td><td>
<table>
<tr><th>Diameter (mm)</th><th>Length (mm)</th></tr>
<tr><td>Ø 4.0</td><td>20-40</td></tr>
<tr><td>Ø 4.5</td><td>25-45</td></tr>
<tr><td>Ø 5.0</td><td>25-50</td></tr>
<tr><td>Ø 5.5</td><td>30-55</td></tr>
<tr><td>Ø 6.5</td><td>30-60</td></tr>
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<table>
<tr><td>Polyaxial Screws</td><td><table><tr><th>Diameter (mm)</th><th>Length (mm)</th></tr><tr><td>Ø 4.5</td><td>30, 35, 40, 45, 50, 55, 60</td></tr><tr><td>Ø 5.0</td><td>30, 35, 40, 45, 50, 55, 60</td></tr><tr><td>Ø 5.5</td><td>30, 35, 40, 45, 50, 55, 60</td></tr><tr><td>Ø 6.0</td><td>30, 35, 40, 45, 50, 55, 60</td></tr><tr><td>Ø 6.5</td><td>30, 35, 40, 45, 50, 55, 60</td></tr></table></td><td><table><tr><th>Diameter (mm)</th><th>Length (mm)</th></tr><tr><td>Ø 4.0</td><td>20-40</td></tr><tr><td>Ø 4.5</td><td>25-70</td></tr><tr><td>Ø 5.0</td><td>30-60</td></tr><tr><td>Ø 5.5</td><td>30-60</td></tr><tr><td>Ø 6.5</td><td>30-60</td></tr></table></td></tr>
<tr><td>Set screw</td><td><table><tr><th>ID (mm)</th><th>OD (mm)</th></tr><tr><td>5.05</td><td>9.90</td></tr></table></td><td><table><tr><th>ID (mm)</th><th>OD (mm)</th></tr><tr><td>5.05</td><td>9.90</td></tr></table></td></tr>
<tr><td>Rod</td><td><table><tr><th>Diameter (mm)</th><th>Length (mm)</th></tr><tr><td>Ø 4.5</td><td>40, 45, 50, 60, 70, 80, 90, 100</td></tr></table></td><td><table><tr><th>Diameter (mm)</th><th>Length (mm)</th></tr><tr><td>Ø 4.5</td><td>30, 40, 50, 60, 70, 80, 90, 100, 200, 480, 600</td></tr></table></td></tr>
<tr><td>Sterilization method</td><td>Non-sterile</td><td>Non-sterile</td></tr>
<tr><td>Performance</td><td>Comply with ASTM F1717</td><td>Comply with ASTM F1717</td></tr>
</table>

11 Similarity and differences

The differences between the proposed device and the predicate device are diameter and length of Monoaxial Screws, Polyaxial Screws and Rod. The proposed device has tested on safety and performance tests and the results were complied with the test requests. Therefore, the differences of proposed device and predicate device did not raise any problems of substantial equivalence. The proposed device is substantially equivalent to the predicate device in intended use, main materials, safety and performance claims.

5.12 Conclusion

After analyzing bench tests, device description and intended use/indications for use, it can be concluded that HC Spinal system is substantially equivalent to the predicate device.