DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 21, 2016

Canwell Medical Co., Ltd.
% Mr. Mike Gu
Regulatory Affairs Manager
Osmunda Medical Device Consulting Co., Ltd
Level 7, Jin Gui Business Center
982 Congyun Road, Baiyun District,
Guangzhou, Guangdong 510420
CHINA

Re: K161151
Trade/Device Name: Spinal fixation system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, KWP, MNI
Dated: September 9, 2016
Received: September 13, 2016

Dear Mr. Gu:

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,

Vincent J. Devlin -S

for
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)*
K161151

Device Name
Spinal fixation system

Indications for Use *(Describe)*
Spinal fixation 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 or 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.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

CANWELL MEDICAL CO., LTD.

No.466 South Xianhua Street, HighTech Industrial

Zone, Jinhua, Zhejiang Province, 321016, P.R. of China

Primary Contact Person: Mike Gu

Regulatory Affairs Manager

OSMUNDA Medical Device Consulting Co., Ltd

Tel: (+86) 20-6232 1333

Fax: (+86) 20-8633 0253

Secondary Contact Person: Chen Hui

CANWELL MEDICAL CO., LTD.

Tel: 86-(0)579-8911-9235

Fax: 86-(0)579-8223-9558

Date Prepared: April 12, 2016

II. DEVICE

Name of Device: Spinal fixation system

Common/Usual Name: Pedicle screw spinal system

Classification Names: 21 CFR 888.3070 Pedicle screw spinal system, 21 CFR 888.3050 Spinal interlaminal fixation orthosis

Regulation Class: II

Product Code: MNH, MNI, KWP

III. PREDICATE DEVICE

Primary predicate: Devine Spinal System K111690;

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Spinal fixation system is mainly constituted by pedicle screw, reduction pedicle screw, Set screw, Spine Hook, Rod and Transverse linking pole assembly. Through using the assembly of the screws, rods and/or poles, there will be established a firm frame structure on the Spinal (conforming to the bio-mechanics principle). The components of the system include: pedicle screw, reduction pedicle screw, set screw, spine hook, rod and transverse linking pole assembly and so on. According to the different specification of the rod's diameter and the different usage on the spinal segments, the system is classified: J2X03, J2X04, J2X07..

V. INDICATIONS FOR USE

Spinal fixation 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 or 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Spinal fixation system employs the same technology as its predicate device K111690. Both have the same indication for use and are made of same raw materials; the bench tests were conducted to verify that the proposed device met all design specifications as was substantially equivalent to the predicate device.

Specification	**Predicate Device** **Devine Spinal System K111690**	**Proposed Device** **Spinal fixation system**
Manufacturer	Changzhou Orthmed Medical Instrument Co., Ltd	CANWELL MEDICAL CO., LTD.

CANWELL MEDICAL LTD.

Class	II
Product Code	MNH, MNI, KWP
Regulation Number	21 CFR 888.3070, 21 CFR 888.3050
Intended Use	The proposed devices of Spinal fixation systems intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients.
Indications for Use	The deivce provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: (1) trauma (i.e. fracure 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.
Patient Population	The device is to be used in skeletally mature patients
Prescription/OTC Use	Prescription use
Static compression bending: yield load	Similar, the testing results show no statistically significant difference between two samples groups
Static compression bending: stiffness	Similar, the testing results show no statistically significant difference between two samples groups
Dynamic compression bending	Similar, the testing results show no statistically significant difference between two samples groups
Static tension bending: yield load	Similar, the testing results show no statistically significant difference between two samples groups
Static tension bending: stiffness	Similar, the testing results show no statistically significant difference between two samples groups
Static torsion: yield torque	Similar, the testing results show no statistically significant difference between two samples groups
Static torsion: torsional stiffness	Similar, the testing results show no statistically significant difference between two samples groups

Materials	Titanium alloy (Ti-Al-4V) which conforms to ASTM F136	Titanium alloy (TiAl-4V) which conforms to ASTM F136
Biocompatibility	Titanium alloy (Ti-Al-4V) which conforms to ASTM F136	Titanium alloy (Ti-Al-4V) which conforms to ASTM F136
Sterility	Provided as non-sterile, needs autoclave prior to use	Provided as non-sterile, needs steam sterilization prior to use

The following technological differences exist between the subject and predicate device:

- Size of components should be chosen based on patient's body size. The size difference between the proposed device and its predicate does not affect their clinical performance.
- The testing results of the static compression bending test, dynamic compression bending test and static torsion test are similar ,however no statistically significant difference between two samples groups

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Mechanical testing

According to the ASTM F1717, the following tests were carried out:

- Static compression bending test
- Dynamic compression bending test
- Static torsion test

Biocompatibility testing:

The Spinal fixation system has permanent contact (>30 days) with bone and tissue.

The Spinal fixation system is made of Ti-6Al-4V. According to the ASTM F136, the materials have been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981.

There is no Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices.

Animal and clinical study

The subject of this premarket submission, Spinal fixation system, does not require clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the performance testing report demonstrate that the Spinal fixation system should perform as intended in the specified use conditions. CANWELL MEDICAL CO., LTD. considers the Pedicle screw spinal system does not raise any new issues of safety or effectiveness.