March 6, 2018

Tianjin Zhengtian Medical Instrument Co., Ltd.
Changli Ou
Regulatory Affairs Specialist
No. 318, Jingyi Road, Airport Economic Zone
Tianjin, 300308
CHINA

Re: K172267
Trade/Device Name: IRENE Thoracolumbar Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: February 8, 2018
Received: February 8, 2018

Dear Changli Ou:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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)*

K172267

Device Name
IRENE Thoracolumbar Fixation System

Indications for Use *(Describe)*
IRENE Thoracolumbar Fixation System 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, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 7 - 510 (k) Summary

A. Date Prepared: Oct. 13th, 2017

B. Submitter and Owner

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Establishment Registration Number: 3010227982

C. Proposed Device

Propriety Name: IRENE Thoracolumbar Fixation System
Common Name: Thoracolumbar Fixation System
Classification: 21 CFR 888.3070 Thoracolumbosacral Pedicle Screw System, Class II
Product Code: NKB

D. Predicate Device

Trade Name: Devine Spinal System
510(k) Number: K111690
Classification Regulation: 21 CFR 888.3070
Product Code: MNH. MNI
Manufacturer: Changzhou Orthmed Medical Instrument Co., Ltd

E. Indications for Use

IRENE Thoracolumbar Fixation System 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, 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.

F. Device Description

The proposed device consists of pedicle screws, reduction screws, titanium rods and transverse connectors in various sizes, providing immobilization and stabilization of spinal segments through bridge connection between these components.

The proposed device is made of titanium alloy per ASTM F136, and is intended for single-use.

The proposed device includes three sub-systems, which are named as PLATINUM 5.5™ Thoracolumbar Fixation System (NS2), TITAN™ 5.5mm Thoracolumbar Fixation System and PLATINUM™ 6.35 Thoracolumbar Fixation System (NS3), all the devices use the same material and similar design principle, there are slight differences in design and parts size among these three sub-systems which does not raise different questions of safety and effectiveness. There is no surface modification or coating.

The proposed devices are supplied non-sterile. It is required to be sterilized via moist heat to reach a SAL of 10^{-6} prior to surgery. The sterilization method is presented in the instructions for use, which has been validated per ISO 17665-1.

G. Technological Characteristic Comparison

The Propose device is found to possess similar technological characteristics under the premises of sharing same intended use after comparing design, material, composition and other aspects, the detailed information is listed in Substantial Equivalence Discussion.

H. Performance Data

Mechanical Testing

Bench tests have been conducted to compare the mechanical properties of the proposed and predicate device according to:

ASTM F1717-15, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

Three tests including static axial compression, dynamic axial compression, and static torsion were conducted according to the methods stipulated in above standard, results indicate that the mechanical properties of proposed device are no lower than that of the predicate device.

Clinical Studies

No clinical data is presented in this submission

I. Conclusion

Based on the technological characteristics and non-clinical performance data, IRENE Thoracolumbar Fixation System is as safe and effective as the predicate device due to same intended use and similar technical characteristics.