June 16, 2020

Shangdong Kangsheng Medical Devices Co., Ltd.
℅ Jonathan Hu
Technical Manager
Medwheat (Shanghai) Medical Technology Co. Ltd.
Yangpu District Liaoyuan East Road Shuangyang First Suite
No. 33 Room 303
Shanghai, 200082 China

Re: K190408
Trade/Device Name: Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 2, 2020
Received: June 12, 2020

Dear Mr. Hu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190408

Device Name
Spinal Fixation System

Indications for Use *(Describe)*
The Spinal Fixation 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.

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Date Prepared: Jun 16th, 2020

510(k) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	Shandong Kangsheng Medical Devices Co., Ltd.
Address:	North of industrial park, Dawenkou Gypsum, 271000, Tai' an, China
Contact Name:	Wenxing Dong
Telephone No.:	+86 0538-8161819
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Email Address:	dwx@sansun.cn

2. Correspondent's Information

Company Name:	Medwheat Shanghai
Correspondent Name:	Jonathan Hu
Telephone No.:	86-021-65181421
Email Address:	Jonathan.hu@medwheat.com

3. Trade Name, Common Name, Classification

Trade / Device Name:	Spinal Fixation System
Common Name:	Pedicle Screw Spinal System
Mode Name:	SF Ⅰ, DF Ⅱ
Regulation Classification:	21 CFR 888.3070 - Thoracolumbosacral pedicle screw system, NKB
Product Code:	
Classification Panel:	Orthopedic
Device Class:	II

4. Identification of Predicate Device(s)

The identified primary predicate within this submission is as follows:

The General Spinal System has been cleared by FDA through 510(k) No. K122994 (Decision Date –April 12, 2013).

5. Description of the Device

The Spinal Fixation System consists of screws, rods, transverse bar assembly, set screws.

It is made of titanium Alloy (Ti6AI4VELI), which meets ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium 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.

6. Intended Use/Indication for Use

The Spinal Fixation 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.

7. Technological Characteristics

Technological Characteristics	Subject Device Spinal Fixation System	Predicate Device General Spinal System K122994	Discussion
Product Code	NKB	MNI MNH KWP	Same*
Regulation	21 CFR 888.3070	21 CFR 888.3050 21 CFR 888.3070	Same
Intended Use	The Spinal Fixation 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.	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; 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.	Same
Material	Ti6Al4V ELI conforms to ASTM F136-13	Ti6Al4V ELI conforms to ASTM F136	Same

510(k) Submission

Technological Characteristics	Subject Device Spinal Fixation System	Predicate Device General Spinal System K122994	Discussion
Test Items	Static Compression Bending Test	Static Compression Bending Test	Same
	Static Torsion Test	Static Torsion Test	
	Dynamic Compression Bending Test	Dynamic Compression Bending Test	
Test Standard	ASTM F1717-15	ASTM F1717-04	Same
How Supplied	Non-sterile	Non-sterile	Same
Sterilization Method	Method: Autoclave	Method: Autoclave	Same
Single Use	Yes	Yes	Same
Prescription / OTC Use	Prescription Use	Prescription Use	Same
*Product Code is consolidated.			

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

The Spinal Fixation System of Shandong Kangsheng Medical Devices Co., Ltd. has taken the sterility and performance testing into concern in accordance to Food and Drug Administration related guidance and recognized international standards. Test data and report information are included in this submission.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shandong Kangsheng Medical Devices Co., Ltd. concludes that Spinal Fixation System is substantially equivalent to predicate devices with regard to safety and effectiveness.