May 8, 2019

Beijing KeYi Medical Device Technology Co., Ltd.
℅ Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120 CN

Re: K190567
Trade/Device Name: KeYi Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: February 22, 2019
Received: March 6, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
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)*
K190567

Device Name
KeYi Spinal Fixation System

Indications for Use *(Describe)*
The proposed KeYi Spinal Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients 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; pseudarthrosis; and/or 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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Tab 7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K190567

1. Date of Preparation: 04/23/2019

2. Sponsor Identification

Beijing KeYi Medical Device Technology Co., Ltd.
Building 1, 30 Yongchang South Road, Beijing Economic Technological Development Area, 100176 Beijing, China

Establishment Registration Number: Not yet registered.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: KeYi Spinal Fixation System
Common Name: Pedicle Screw Spinal System

Regulatory Information
Classification Name: Thoracolumbosacral Pedicle Screw System
Classification: II
Product Code: NKB
Regulation Number: 21 CFR 888.3070
Review Panel: Orthopedic

Indications for Use:
The proposed KeYi Spinal Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients 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; pseudarthrosis; and/or failed previous fusion.

Device Description

The KeYi Spinal Fixation System implant consists of a variety of shapes and sizes of rods, screws and cross-connectors which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The proposed device is made of Titanium Alloy (Ti6Al4V) which meets ASTM F136-13 and CoCrMo which meets ASTM F1537-11.

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. Identification of Predicate Device

Primary Predicate Device
510(k) Number: K012871
Product Name: SYNERGY TI INTEGRAL OPEN SCREWS
Manufacturer: INTERPORE CROSS INTL.

Additional Predicate Device
510(k) Number: K111942
Product Name: TSRH
Manufacturer: Medtronic

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F 1717-15, 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.

510(k) Summary

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Proposed Device and Predicated Device

Item	**Proposed Device**	**Predicate Device 1** **K012871**	**Predicate Device 2** **K111942**
Product Code	KWP	KWP	KWP
Regulation Number	21 CFR 888.3050	21 CFR 888.3050	21 CFR 888.3050
Class	II	II	II
Indications for Use	The proposed KeYi Spinal Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients 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; pseudarthritis; and/or failed previous fusion.	The Synergy Spinal System implants are intended to be used as a temporary construct that assists normal healing and are not intended to replace normal body structures. They are intended to stabilize the spinal operative site during fusion procedures and should be removed after fusion. The implants are attached to the spine posteriorly by means of hooks and/or screws joined with rods and anteriorly by means of vertebral screws joined with rods. As a pedicle screw system, the Synergy Spinal System is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are having the screws fixed or attached to the lumbar and sacral spine; (c) who are receiving fusions using autogenous bone graft only;	When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients using allograft and/or autograft, the TSRH Spinal system is indicated as an adjust to fusion for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis). In addition, when used as a pedicle screw fixation system, the TSRH

		and (d) who are having the device removed after the development of a solid fusion mass. The levels of screw fixation are L3 to S/Ilium. In addition, the pedicle screw system may also be used to provide immobilization and stabilization of spinal segments, in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).	Spinal System is indicated as an adjunct to fusion for skeletally mature patients using allograft and/or autograft: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only:(3) who are having the device fixed or attached to the lumbar and sacral spine(L3 and below): and (4) who are having the device removed after the development of a solid fusion mass.
Components	Multi-axial screw	VLS Open Screw	Variable Angle Screw
	Mono-axial screw	Close Screw	
	Multi-axial reduction screw	VLS Open Reduction Screw	
	Mono-axial reduction screw	Close Reduction Screw	
	Uni-planar reduction screw	Angled Closed Reduction Screw	
	Multi-axial cannulated reduction screw	/	Multi-axial cannulated reduction screw
	Mono-axial cannulated reduction screw	/	Mono-axial cannulated reduction screw
	Mono-axial cannulated reduction screw	/	Mono-axial cannulated reduction screw

	Rod	Ti Rod	Ti Rod, CoCrMo Rod and SS Rod
	Set screw	Set screw	Lock screw
	Cross connector	Cross connector	Crosslink

The proposed device has three more types of screws than the predicate device, which are multi-axial cannulated reduction screw, mono-axial cannulated reduction screw and cannulated Uni-planar reduction screw. The configuration of predicates can cover that of proposed device, and the performance of proposed device has been tested per ASTM F1717 and the test results shows the performance of proposed device is not inferior to that of predicate. Therefore, this difference is determined not to affect the Substantially Equivalency (SE) between the proposed device and predicate device concerning the safety and effectiveness of the medical device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.