June 21, 2021

Shanghai REACH Medical Instrument Co., Ltd
Mingsha Ye
Registration Manager
Building 13, No. 999 Jiangyue Road, Minhang
Shanghai, 201112
China

Re: K201737/S001
Trade/Device Name: Posterior Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 24, 2020
Received: June 25, 2020

Dear Mingsha Ye:

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.
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)*

K201737

Device Name
Posterior Spinal Fixation System

Indications for Use *(Describe)*

The Posterior Spinal Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion 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.

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510(k) Summary

510(k) Number:	K201737	
Preparation Date:	December 28, 2020	
Submitter:	Shanghai REACH Medical Instrument Co., Ltd Building 13,No.999 Jiangyue Road, Minhang District, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA Establishment Registration Number: 3015487912	
Primary Contact:	Mingsha Ye, Registration Manager Shanghai Reach Medical Instrument Co., Ltd Building 13,No.999 Jiangyue Road, Minhang District, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA Email: yems@reach-med.com Tel: (86) 021-54840582 Fax: (86) 021-54840581	
Subject Device:	Trade Name	Posterior Spinal Fixation System
	Common Name	Thoracolumbosacral Pedicle Screw System
	Regulation Number	21 CFR 888.3070
	Classification Name	Thoracolumbosacral Pedicle Screw System
	Regulatory Class	Class II
	Product Codes	NKB
	Regulation Medical Specialty	Orthopedic
	510(k) Review Panel	Orthopedic
Predicate Device:	Manufacturer	Medtronic Sofamor Danek USA, Inc.
	Trade Name	CD HORIZON® Spinal System
	510(k) Number	K130646
	Regulation Number	21 CFR 888.3070
	Regulation Name	Thoracolumbosacral Pedicle Screw System
	Regulatory Class	Class II
	Product Codes	NKB, KWP, KWQ, MNH, MNI
	Regulation Medical Specialty	Orthopedic
	510(k) Review Panel	Orthopedic
FDA Guidance Documents	The following FDA guidance documents were consulted to prepare this premarket notification: • *Guidance for Industry and FDA Staff: Spinal System 510(k)s*, issued May 3, 2004 • *Guidance on Medical Device Patient Labeling*, issued April 19, 2001 • *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued March 17, 2015 • *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, issued June 16, 2016 • *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*, issued December 11, 2014	

Intended Use / Indications for Use	The Posterior Spinal Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion 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 Posterior Spinal Fixation System is a single-use system for surgical fixation of the spine. It is made up of pedicle screws, rods, and interconnecting devices. The implanted parts confer stabilization and fusion of two or more spinal segments and are to be removed once their stabilizing function is no longer required. The implantable devices are manufactured from titanium alloy and are provided non-sterile. The Posterior Spinal Fixation System includes the following sets: • RS8 LEGEND (designed for open surgery) • RS8 LONG (designed for minimally invasive surgery) Each set comprises of different rods, screws, set screws, and accessory parts, including various lengths and diameters of reduction screws. Both sets are designed for internal posterior thoracolumbar fixation of the spine. Patient diagnosis and individual conditions should be taken into consideration when selecting the surgical option.	
Mechanism of Action	The Posterior Spinal Fixation System is a medical device system for surgical fixation of the spine. It is made up of pedicle screws, rods, and interconnecting devices. The implanted parts confer stabilization and fusion of two or more spinal segments and are to be removed once their stabilizing function is no longer required.	
Applicant	Shanghai REACH Medical Instrument, Co., Ltd.	Medtronic Sofamor Danek USA, Inc.
Device Name	Posterior Spinal Fixation System	CD HORIZON® Spinal System

Intended Use / Indications for Use	The Posterior Spinal Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion 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.	The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion 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. Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion. With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications below. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: Spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. The CD HORIZON SPIRE™ Plate is a posterior, single level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving

			supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis; trauma; and/or tumor. In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.
Patient Population		Skeletally mature patients; Pediatric patients	Skeletally mature patients; Pediatric patients
Anatomical Site		Thoracolumbosacral spine	Thoracolumbosacral spine
Mechanism of Action		The Posterior Spinal Fixation System is a medical device system for surgical fixation of the spine. It is made up of pedicle screws, rods, and interconnecting devices. The implanted parts confer stabilization and fusion of two or more spinal segments and are to be removed once their stabilizing function is no longer required.	The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screw, CROSSLINK® plates, staples, and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.
Implant Materials		Titanium alloy (Ti-6Al-4V)	Stainless steel, titanium, titanium alloy, cobalt-chromium-molybdenum alloy, PEEK, and/or nitinol
Surgical Instrument Materials		Stainless steel (17-4 PH) Silica gel Polyformaldehyde (POM) Aluminum alloy	Unknown
Coatings/Colorants:		Components are colored via an anodizing process. No other coatings or colorants are added to the device.	Components are colored via an anodizing process. No other coatings or colorants are added to the device.
Patient Contact		Implant: Bone and surrounding tissue Surgical instruments: Bone and surrounding tissue	Implant: Bone and surrounding tissue Surgical instruments: Bone and surrounding tissue
Contact Duration		Implant: Permanent (>30 days) Surgical instruments: Limited (≤24 hours)	Implant: Permanent (>30 days) Surgical instruments: Limited (≤24 hours)
Provided Sterile?		Implant: No Surgical Instruments: No	Implant: No Surgical Instruments: No
Sterilization Method		The device is provided non-sterile. Validated manual cleaning and steam sterilization instructions are provided for the end user.	The device is provided non-sterile. Validated manual cleaning and steam sterilization instructions are provided for the end user.
Single Use		Implant: Yes Surgical Instruments: No	Implant: Yes Surgical Instruments: No
Surgical Instruments Provided		Yes	Yes
Environment of Use		Healthcare facility/Hospital	Healthcare facility/Hospital
Rods	Diameter Range	5.5-6.0mm	3.5-6.0mm

	Length Range	40-500mm	500mm
Set Screws	Diameter Range	9.5-10mm	6.0-10mm
Crosslinks	Diameter Range	5.0-6.0mm	3.5-6.0mm
	Length Range	23-80mm	13-120mm
Polyaxial Reduction Screws	Diameter Range	4.5-7.5mm	4.0-8.5mm
	Length Range	25-90mm	20-115mm
MISS Polyaxial Reduction Screws	Diameter Range	4.5-10mm	4.0-8.5mm
	Length Range	25-110mm	20-115mm
MR Safety and Compatibility		Not evaluated	MR conditional
Performance – Bench		The following testing standards were utilized to complete bench performance testing: ASTM F1717-18 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model • Static Compression: The compressive bending yield load of the subject device is lower than the predicate device. The compressive bending ultimate load of the subject device is higher than the predicate device. • Dynamic Compression: The subject device experienced more fractures than the predicate device. • Static Tensile: The tensile bending ultimate load of the subject device is lower than the predicate device. • Static Torsion: The yield torque and torsional stiffness of the subject device are lower than the predicate device. ASTM F1798-13 Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants • Axial Gripping Capacity • Axial Torque Gripping Capacity • Static A-P • Dynamic A-P • Static Transverse • Dynamic Transverse	

Characterization Testing	The following testing standards were utilized to characterize the materials: • ISO 5832-3 Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4- vanadium alloy • ASTM E1409-13 Standard Test Method for Determination of Oxygen and Nitrogen in titanium and titanium Alloys by Inert Gas Fusion • ASTM E1447-09(2016) Standard Test Method for Determination of Hydrogen in titanium and titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method • ASTM E1941-10 Standard Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis • ASTM E2371-13 Standard Test Method for Analysis of titanium and titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology) • GB/T 5168-2008 Microstructure And Macrostructure Examination For α-β titanium Alloys • GB/T 13810-2007 Wrought Titanium and Titanium Alloy for Surgical Implants • GB/T 5193-2007 Method of ultrasonic inspection for wrought titanium and titanium alloy products
Biocompatibility Testing	The following testing standards were utilized for biocompatibility test: • ISO/IEC 17025-2005: General requirements for the competence of testing and calibration laboratories; • ISO 10993-5:2009: Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity; • ISO 10993-10:2010: Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization; • ISO 10993-11:2017: Biological evaluation of medical devices-Part 11: Tests for Systemic toxicity; • ISO 10993-12:2012: Biological evaluation of medical devices-Part 12: Sample preparation and reference materials; • ISO/TS 21726:2019: Biological evaluation of medical devices-Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents; • ISO 10993-1:2018: Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process; • ISO 10993-17:2002: Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances; • ISO 10993-18:2020: Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials within a risk management process; • ISO 14971:2019: Medical devices-Application of risk management to medical devices. • ISO/IEC 17025-2017: General requirements for the competence of testing and calibration laboratories.
Performance – Animal	No animal study data is submitted in this 510(k).
Performance – Clinical	No clinical study data is submitted in this 510(k).

Substantial Equivalence	The Posterior Spinal Fixation System is substantially equivalent to the predicate device when evaluating intended use and technological characteristics. • The subject device has the identical intended use as the predicate device. There are no differences between the subject device and predicate device with respect to intended use. The subject has different indications for use than the predicate device. • The subject device and predicate devices are substantially equivalent with only minor differences regarding: o Product codes o Indications for use o Mechanism of action o Materials o Rods o Set screws o Crosslinks o Polyaxial reduction screws o MISS polyaxial reduction screws o Bench performance results: static compression, dynamic compression, static tensile, and static torsion • These differences do not raise new questions of safety and effectiveness.
Conclusion	Non-clinical data demonstrates the Posterior Spinal Fixation System device is substantially equivalent to the predicate device. The subject device is as safe and effective as the predicate device, and will perform as intended. Therefore, SRMIC respectfully requests market clearance for the Posterior Spinal Fixation System.