August 31, 2022

Shanghai REACH Medical Instrument Co., Ltd.
% Huifang Zhao
Consultant
Sinow Medical AS
Hoyteknologisenteret, Thormohlens gate 55
Bergen, 5006
Norway

Re: K221745
Trade/Device Name: Sterile Posterior Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 19, 2022
Received: August 24, 2022

Dear Huifang Zhao:

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,

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221745

Device Name
Sterile Posterior Spinal Fixation System

Indications for Use *(Describe)*
The Sterile 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

K221745

1. Contact Information

1.1. Applicant

Date prepared: Aug.19,2022
Applicant: Shanghai REACH Medical Instrument Co., Ltd
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1.2. Consultant

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2. Device information

Trade Name: Sterile Posterior Spinal Fixation System
Common Name: Thoracolumbosacral Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Classification Name: Thoracolumbosacral Pedicle Screw System
Classification: II
Product Code: NKB
Review Panel: Orthopedic

3. Legally Marketed Primary Predicate Device

Posterior Spinal Fixation System (K201737)

4. Indications for use

The Sterile 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.

5. Device Description

The Sterile 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 sterile.

The Sterile 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.
Surgical instruments are provided with the subject device and predicate device.

The subject of this submission is a design change to Posterior Spinal Fixation System(K201737). The Posterior Spinal Fixation System(K201737) is provided non-sterile and the subject device is provided sterile.

6. Substantially Equivalent (SE) Comparison

The subject device has the same indications for use/intended use, design, and materials as the primary predicate device. The only change proposed in this submission is the method used to sterilize the subject device.

7. Description of the change

The modification has been made only to sterilization method of the implants. The predicate device provides non-sterile implants and surgical instruments which must be cleaned and sterilized by the end user prior to use. For the subject device the implants are sterilized with gamma sterilization by manufacture and the sterilization process was validated according to ISO 11137-1:2006 and AAMI TIR29:2012. The implants will provide a sterility assurance level (SAL) of 10^{-6}.

8. Performance data

The evaluation of biocompatibility, sterility, pyrogenicity, package integrity, and shelf-life were performed in support of the proposed change.

No additional pre-clinical or clinical data is required to support the substantial equivalence determination for this change.

9. Conclusion

The information presented in this 510(k) submission establishes that the subject device is substantially equivalent to the primary predicate device.