November 29, 2023

Shanghai REACH Medical Instrument Co., Ltd.
℅ Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K232069
Trade/Device Name: Expandable Lumbar Fusion Cage (Type I,Type II)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 27, 2023
Received: October 27, 2023

Dear Eva Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Brent Showalter -S

Brent Showalter, Ph.D.
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.

Submission Number *(if known)*

K232069

Device Name

Expandable Lumbar Fusion Cage (Type I, Type II)

Indications for Use *(Describe)*

Expandable Lumbar Fusion Cage (Type Ⅰ, Type Ⅱ) are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine(L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).
Expandable Lumbar Fusion Cage (Type Ⅰ, Type Ⅱ) are to be filled with autogenous bone graft material. This device is intended to be used with supplemental fixation, such as the Posterior Spinal Fixation System.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Date Prepared: Oct 26th, 2023

1. Submitter information

Company: Shanghai REACH Medical Instrument Co., Ltd.
Building 13, No.999 Jiangyue Road, Minhang District, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Contact: Jian Shen
shenj@reach-med.com
00862154840582

2. Device information

Device Name: Expandable Lumbar Fusion Cage
(Type I, Type II)

Classification: 21 CFR 888.3080 Intervertebral Body Fusion device

Code: MAX

Class: II

Medical Specialty: Orthopedic

3. Predicate Device information

K113447
RISE ™ Spacer
Globus Medical Inc

4. Device Description

The Expandable Lumbar Fusion Cage system is a kind of fusion device for thoracolumbar and spinal stability. The main indication of this product is spinal fusion for spinal operation. The components of system are made of titanium alloy. The Expandable Lumbar Fusion Cage system is used by trained orthopaedic surgeons and/or neurosurgeons in a standard operating environment. The Expandable Lumbar Fusion Cage system provides a wide range of implants, including different widths, heights, lengths and angles to choose from.

5. Indication for use

Expandable Lumbar Fusion Cage (Type I, Type II) are lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Expandable Lumbar Fusion Cage (Type I, Type II) are to be filled with autogenous bone graft material. This device is intended to be used with supplemental fixation, such as the Posterior Spinal Fixation System.

6. Summary of Technological Characteristics

The Shanghai REACH Expandable Lumbar Fusion Cage (Type I, Type II) are identical or similar to the cited predicate systems in regard to intended use/indications for use, device description, technological characteristics (e.g., operating principle, design, components, materials, manufacturing, labelling, sterility, etc.), and non-clinical performance (i.e., mechanical testing).

7. Performance Data

Mechanical testing (static and dynamic compression, static and dynamic compression-shear per ASTM F2077 and subsidence per ASTM F2267) was conducted to demonstrate substantial equivalence to the predicate device.

8. Basis for Substantial Equivalence

The Expandable Lumbar Fusion Cage (Type I, Type II) has been found to be substantially equivalent to the predicate device under K113447 with respect to technical characteristics, performance, design, materials and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device.