March 3, 2023

Changzhou Geasure Medical Apparatus and Instruments Co., Ltd
% Xiaoqing Xue
Registration Engineer
Sinow Medical AS
Vestre Fantoftasen 44, 5072, Bergen
Norway

Re: K223776
Trade/Device Name: PEEK Spinal Fusion Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 30, 2022
Received: January 3, 2023

Dear Xiaoqing Xue:

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,

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.

510(k) Number *(if known)*
K223776

Device Name
PEEK Spinal Fusion Cage

Indications for Use *(Describe)*
The PEEK Spinal Fusion Cage is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. 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 six months of non-operative treatment. These implants are to be used with autogenous bone graft.
The PEEK Spinal Fusion Cage may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an transforaminal approach.
These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by FDA for use in the lumbar spine.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

6. 510(K) Summary

Preparation Date:	December 30, 2022	
Submitter:	Changzhou Geasure Medical Apparatus and Instruments Co., Ltd No. 12, Jinfeng Road, West Taihu Science and Technology Industrial Park, Changzhou, Jiangsu, P.R. China	
Primary Contact	Jing Huang, Management Representative Changzhou Geasure Medical Apparatus and Instruments Co., Ltd No. 12, Jinfeng Road, West Taihu Science and Technology Industrial Park, Changzhou, Jiangsu, P.R. China Postcode: 213149 Email: huangjing@geasure.com Phone:+86 13656146897	
Designated Submission Correspondent	Company: Sinow Medical AS Address: Vestre Fantoftåsen 44, 5072, Bergen, Norway Contact Person: Xiaoqing Xue Telephone: +86 15161196032 Email: xue@bergemed.com	
Subject Device	Trade name	PEEK Spinal Fusion Cage
	Common name	Intervertebral Body Fusion Device
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Product Codes	MAX
	Classification Panel	Orthopedic
	Classification Name	Intervertebral Fusion Device With Bone Graft. Lumbar
Primary Predicate Device	Manufacturer	Medtronic Sofainor Danek USA, Inc.
	Trade name	CAPSTONE® Spinal System
	510(K) Number	K073291
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Product Codes	MAX
	Classification Panel	Orthopedic
	Classification Name	Intervertebral Fusion Device With Bone Graft. Lumbar
FDA Guidance Documents	The following FDA guidance documents were consulted to prepare this premarket notification: • Guidance on Medical Device Patient Labeling, issued April 19, 2001 • Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued 2020	
Intended Use / Indications for Use	The PEEK Spinal Fusion Cage is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease	

	(DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. 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 six months of non-operative treatment.These implants are to be used with autogenous bone graft. The PEEK Spinal Fusion Cage may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.
Device Description	The PEEK Spinal Fusion Cage consists of INVIBIO PEEK-OPTIMA LTI lumbar cages of various lengths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.The cages contain radiographic tantalum markers used for both intra and post-operative positioning and visualization. The implants are single-use and non-sterile provided.
Mechanism of Action	The PEEK Spinal Fusion Cage consists of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. It is intended to stabilize spinal segment to promote fusion in order to restrict motion and decrease pain using bone graft.
Materials	PEEK cages and Tantalum markers
Patient Contact	Bone and surrounding tissue
Contact Duration	Permanent (>30 days)
Sterilization Method	The devices are provided non-sterile; validated manual cleaning and steam sterilization instructions are provided for the end user before implantation.
Environment of Use	Healthcare facility/Hospital
Single Use	Yes
Length	22-36 mm
height	8-16 mm
features	a convex, bullet nose design
	angular teeth
	hollow geometry
Material Characterization testing	The following testing standards were utilized to characterize the materials: • ISO 13782:2019 Implants for surgery - Metallic materials - Unalloyed tantalum for surgical implant applications

	• ASTM F2026-17 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
Biocompatibility Testing	The following testing standards were utilized to evaluate biocompatibility of the materials: • ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process • ISO 10993-3:2014 Biological evaluation of medical devices -- Part 3:Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity • ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity • ISO 10993-6: 2016 Biological evaluation of medical devices - Part 6:Tests for Local Effects After Implantation • 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: test for systemic toxicity • ISO 10993-12:2012 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials • ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices • ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of materials
Performance - Bench	The following testing standards were utilized to complete bench performance testing: • ASTM F2077-18 Test Methods for Intervertebral Body Fusion Devices • ASTM F2267-04 (Reapproved 2018) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
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 PEEK Spinal Fusion Cage 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. The subject device and predicate devices are substantially equivalent with only minor differences regarding: • Device sterilization method • Bench performance: static and dynamic compression, static and dynamic compression-shear and subsidence test These differences do not raise new questions of safety and effectiveness.

Conclusion	Non-clinical data demonstrates the PEEK Spinal Fusion Cage is substantially equivalent to the predicate device.