October 28, 2022

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

Re: K222031
Trade/Device Name: Spinal Inner Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: October 6, 2022
Received: October 7, 2022

Dear Ms. 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,

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)*
K222031

Device Name
Spinal Inner Fixation System

Indications for Use *(Describe)*
Spinal Inner Fixation System is intended for posterior, non-cervical, pedicle fixation 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 device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft.

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

K222031

Preparation Date:	Oct. 06, 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 Jing Huang, Management Representative 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	Spinal Inner Fixation System
	Common name	Pedicle Screw Spinal System
	Regulatory Class	II
	Regulation Number	21 CFR 888.3070
	Product Codes	NKB
	Classification Panel	Orthopedic
	Classification Name	Thoracolumbosacral Pedicle Screw system
Primary Predicate Device	Manufacturer	Changzhou Dingjian Medical Appliance Co., Ltd.
	Trade name	Spinal Inner Fixation System
	510(K) Number	K143013
	Regulatory Class	II
	Regulation Number	21 CFR 888.3070,888.3050
	Product Codes	MNH, MNI, KWP
	Classification Panel	Orthopedic
	Classification Name	Thoracolumbosacral Pedicle Screw System, Spinal Interlaminal Fixation Orthosis
Intended Use / Indications for Use	Spinal Inner Fixation System is intended for posterior, non-cervical, pedicle fixation 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 device is to be used in skeletally mature patients, and for stabilization and immobilization of the spine as an adjunct to fusion with bone graft.
Device Description	The Spinal Inner Fixation System is a medical device system for surgical fixation of the spine. It is made up of pedicle screws, set screw, rods and cross connecting 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 implants are single-use. The surgical instruments may be reprocessed and re-used. The Spinal Inner Fixation System includes model GB1Z-I and GB1Z-II according to the rod diameter, and each model comprises of different length rods, various length and diameter screws, set screws and accessories. Both models 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 device system.
Materials	Titanium alloy (Ti-6Al-4V) ELI
Coatings/Colorants	The devices are colored using an anodizing manufacturing process. No coatings or colorants are added to the device with this process.
Sterilization Method	The devices are provided non-sterile; validated manual cleaning and steam sterilization instructions are provided for the end user before implantation.
Performance - Bench	The ASTM F1717-18 standards were utilized to complete the following bench performance testing on the subject and predicate device: • static compression bending • dynamic compression bending, • static torsion
Substantial Equivalence	The Spinal Inner 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.

	The subject device and predicate devices are substantially equivalent with only minor differences regarding: • Mechanism of action • Rods • Set screw • Cross connector • Bench performance: static compression, dynamic compression and static torsion These differences do not raise new questions of safety and effectiveness.
Conclusion	Non-clinical data demonstrates the Spinal Inner Fixation System device is substantially equivalent to the predicate device.