June 30, 2023

Changzhou Geasure Medical Apparatus and Instruments Co., Ltd
℅ Xiaoqing Xue
Registration Engineer
Sinow Medical AS
Høyteknologisenteret, Thormøhlens Gate 55, 5008
Bergen, Norway

Re: K230456
Trade/Device Name: SGM Femoral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: June 27, 2023
Received: June 27, 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2023.06.30 08:56:29 -04'00'

For: Farzana Sharmin, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*
K230456

Device Name
SGM Femoral Nail System

Indications for Use *(Describe)*
SGM Femoral Nail System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The long SGM Femoral Nail is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.

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."

510(K) Summary

K230456

Preparation Date:	May.29, 2023	
Submitter:	Changzhou Geasure Medical Apparatus and Instruments Co., Ltd. Address: No. 12, Jinfeng Road, West Taihu Science and Technology Industrial Park, Changzhou, Jiangsu, P.R. China	
Applicant Contact	Jing Huang, Management Representative Changzhou Geasure Medical Apparatus and Instruments Co., Ltd. Address: 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: Høyteknologisenteret, Thormøhlens Gate 55, 5008, Bergen, Norway Contact Person: Xiaoqing Xue Telephone: +86 15161196032 Email: xue@bergemed.com	
Subject Device	Name of Device	SGM Femoral Nail System
	Regulatory Class	II
	Regulation Number	21 CFR 888.3020 and 888.3040
	Product Codes	HSB, HWC
	Classification Name	Intramedullary fixation rod; Smooth or threaded metallic bone fixation fastener
	Classification Panel	Orthopedic
	Common Name	Rod, Fixation, Intramedullary And Accessories; Screw, Fixation, Bone
Primary Predicate Device	Manufacturer	Synthes (USA)
	Name of Device	Synthes (USA) Trochanteric Fixation Nail (TFN) System
	510(K) Number	K011857
	Regulatory Class	II
	Regulation Number	21 CFR 888.3020 and 888.3040
	Product Codes	HSB, HWC
	Classification Name	Intramedullary fixation rod; Smooth or threaded metallic bone fixation

		fastener
	Classification Panel	Orthopedic
	Common Name	Rod, Fixation, Intramedullary And Accessories; Screw, Fixation, Bone
Intended Use / Indications for Use	SGM Femoral Nail System is intended to treat stable and unstable fractures of the proximal femur including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The long SGM Femoral Nail is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal non-unions, malunions, and revisions.	
Device Description	An intramedullary fixation nail is a metal rod implanted into the medullary cavity of a bone to treat fractures that occur in long bones of the body. SGM Femoral Nail System consists of a series of metal rods, proximal helical blades, bone locking bolts and end caps. The rods are cannulated and are provided with screw holes to accommodate screws of various diameters and lengths. The rods are available in a range of sizes used for specific anatomic locations and fracture configurations. The implantable devices are manufactured from titanium alloy and are provided non-sterile.	
Mechanism of Action	The SGM Femoral Nail System permits an intramedullary approach for the fixation of fractures of the femur. The SGM Femoral Nail System consists of a series of cannulated nails, cannulated helical blades, cannulated end caps, and locking bolts. The helical blade provides resistance to varus collapse and rotational control of the medial fracture segment compared to single screw fixation. The end cap is designed for proximal closure of the nail to prevent bone ingrowth.	
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.	
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	
End cap	Length: 0mm, 5mm and 10mm	
Helical Blades	Length:75mm-120mm Diameter:Ø11mm	

Locking bolt	Length:26mm-100mm Diameter: Ø4.9mm
Intramedullary fixation nails	Length:short 170mm, 200mm and 235mm; long 320mm-420mm Diameter: Ø10mm, Ø11mm,Ø12mm
angle	130°
Performance - Animal	No animal study data is submitted in this 510(k).
Summary of intended use and technological characteristics	The SGM Femoral Nail 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 in technological characteristics regarding: • Intramedullary Fixation Nail size • Helical Blade size • Locking Bolt size These differences do not raise different questions of safety and effectiveness.
Non-clinical test	• Performance-bench test including: Static Four-Point Bending Test per ASTM F1264-16 Static Torsional Test per ASTM F1264-16 Bending Fatigue Test per ASTM F1264-16 Bending Fatigue Test of Locking Screws per ASTM F1264-16 Cut-out Test of Helical Blade per ASTM F1264-16 Torsional Properties Test of the Locking Bolt per ASTM F543-17 Driving Torque Test of the Locking Bolt per ASTM F543-17 Axial Pullout Strength Test of the Locking Bolt per ASTM F543-17 Self-Tapping Performance Test of the Locking Bolt per ASTM F543-17 Single Cycle Construct Strength Test per ASTM F384-17 Construct Fatigue Strength Test per ASTM F384-17 •Reprocessing and sterilization SGM Femoral Nail System must be cleaned and sterilized prior to use. Geasure completed manual cleaning and steam sterilization validation testing per FDA guidance document, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued March 17, 2015. Validation testing confirmed the reprocessing instructions provided by Geasure achieve sterility of the implant and surgical instruments prior to use.
Performance - Clinical	No clinical study data is submitted in this 510(k).
Conclusion	The non-clinical data demonstrates the SGM Femoral Nail System is substantially equivalent to the predicate device.