December 15, 2023

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

Re: K232394
Trade/Device Name: Internal Locking Plate and Screw Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 13, 2023
Received: November 13, 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 (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232394

Device Name
Internal Locking Plate and Screw Fixation System

Indications for Use *(Describe)*

Internal Locking Plate and Screw Fixation System is intended for temporary fixation, correction or stabilization of bones in various anatomical regions.

3.5mm LCP Clavicle Plate
3.5mm LCP Clavicle Plate is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle.

3.5mm LCP Proximal Humeral Plate
LCP Proximal Humerus Plate is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

3.5mm LCP Distal Humerus plate
3.5mm LCP Distal Humerus plate is indicated for intraarticular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

2.4mm LCP Volar Distal Radius Plate
2.4 mm LCP Volar Distal Radius Plate is indicated for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

5.0mm LCP Distal Femur Plate
5.0 LCP Distal Femur Plate is indicated for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, nonunions and malunions, and osteotomies of the femur.

3.5mm LCP Medial Proximal Tibial Plate
3.5mm LCP Medial Proximal Tibia Plate is indicated to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. Also, for use in the fixation of osteopenic bone and fixation of nonunions and malunions of the medial proximal tibia and tibia shaft.

3.5mm LCP Anterolateral Distal Tibia Plate
3.5mm LCP Anterolateral Distal Tibia Plate is indicated for fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone.

2.7mm/3.5mm LCP Distal Fibula Plate
2.7mm/3.5mm LCP Distal Fibula Plate is indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.

2.0mm LCP Condylar Plate
2.0mm LCP condylar Plate is indicated for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle.

3.5mm Round Hole Reconstruction Locking Plate

The 3.5mm Round Hole Reconstruction Locking Plates is indicated for fixation of fractures, osteotomies and non-unions of the pelvis, particularly in osteopenic bone for adult patients.

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

K232394

Preparation Date:	Dec. 09, 2023	
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	
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	Internal Locking Plate and Screw Fixation System
	Regulatory Class	II
	Regulation Number	21 CFR 888.3030, 21 CFR 888.3040
	Classification Panel	Orthopedic
	Classification Name	Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener;
	Product Codes	HRS, HWC
	Common name for product codes	HRS:Plate Fixation, Bone HWC: Screw, Fixation, Bone
Primary Predicate Device	Manufacturer	DePuy Synthes
	Trade name	Synthes (USA) Modular Mini Fragment LCP System;
	510(K) number	K063049
	Regulatory Class	II
	Regulation Number	21 CFR 888.3030, 21 CFR 888.3040
	Classification Panel	Orthopedic
	Classification Name	Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener;
	Product Codes	HRS, HWC
	Common name for	HRS:Plate Fixation, Bone

	product codes	HWC: Screw, Fixation, Bone
Additional Predicate Devices	Manufacturer	DePuy Synthes
	Trade name /510(K) number	K073186, Synthes 3.5mm LCP Clavicle Plate System;
		K011815, Synthes LCP Proximal Humerus Plate;
		K033995, 3.5mm LCP Distal Humerus System;
		K083694, Synthes 2.4mm VA-LCP Two-Column Volar Distal Radius Plate;
		K062564, Synthes LCP Distal Femur Plate;
		K032269, Synthes (USA) 3.5/4.5mm LCP Medial Proximal Tibia Plates;
		K092812, Synthes (USA) 2.7mm /3.5mm LCP Anterolateral Distal Tibia Plates;
		K083213, Synthes 2.7mm/3.5mm LCP Distal Fibula Plates-Modification;
		K082807, Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications
	Regulatory Class	II
	Regulation Number	21 CFR 888.3030, 21 CFR 888.3040
	Product Codes	HRS, HWC
	Classification Panel	Orthopedic
	Classification Name	Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener;
Reference device	Manufacturer	Changzhou Geasure Medical Apparatus and Instruments Co., Ltd
	Trade name	Spinal Inner Fixation System
	510(K) number	K222031
	Regulatory Class	II
	Regulation Number	21 CFR 888.3070
	Product Codes	NKB
	Classification Panel	Orthopedic
	Classification Name	Thoracolumbosacral Pedicle Screw system
Intended use/indications for use	Internal Locking Plate and Screw Fixation System is intended for temporary fixation, correction or stabilization of bones in various anatomical regions. **3.5mm LCP Clavicle Plate** 3.5mm LCP Clavicle Plate is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle. **3.5mm LCP Proximal Humeral Plate** LCP Proximal Humerus Plate is indicated for fractures and fracture	

	dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone. **3.5mm LCP Distal Humerus plate** 3.5mm LCP Distal Humerus plate is indicated for intraarticular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus. **2.4mm LCP Volar Distal Radius Plate** 2.4 mm LCP Volar Distal Radius Plate is indicated for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones. **5.0mm LCP Distal Femur Plate** 5.0 LCP Distal Femur Plate is indicated for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, nonunions and malunions, and osteotomies of the femur. **3.5mm LCP Medial Proximal Tibial Plate** 3.5mm LCP Medial Proximal Tibia Plate is indicated to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. Also, for use in the fixation of osteopenic bone and fixation of nonunions and malunions of the medial proximal tibia and tibia shaft. **3.5mm LCP Anterolateral Distal Tibia Plate** 3.5mm LCP Anterolateral Distal Tibia Plate is indicated for fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone. **2.7mm/3.5mm LCP Distal Fibula Plate** 2.7mm/3.5mm LCP Distal Fibula Plate is indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone. **2.0mm LCP Condylar Plate** 2.0mm LCP condylar Plate is indicated for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone. Examples include, but are not limited to, the hand, wrist, foot, and ankle. **3.5mm Round Hole Reconstruction Locking Plate** The 3.5mm Round Hole Reconstruction Locking Plate is indicated for fixation of fractures, osteotomies and non-unions of the pelvis, particularly in osteopenic bone for adult patients.
Device Description	Internal Locking Plate and Screw Fixation System consists of plates in various designs and size. Plates are provided in straight designs and

	various geometric configurations that are commonly used in traumatic and reconstructive surgery. Plates are provided with screw holes to accommodate non-locking and locking screws. They are named according to both anatomical positions and biomechanical functions of the plates. The Internal Locking Bone Plate and Screw Fixation System is divided into four types: large, small, mini, and reconstruction. The length of the plate varies from 45 to 316mm, and hole number from 3 to 22 holes. Geasure Internal Locking Bone Screw System is used either to fasten plates or similar devices onto bones or to hold bone fragments together. The screws are differentiated by the manner in which they are inserted into bone, their function, their size, and the type of bone they are intended for. There are two styles: locking screw, cortex or cancellous screw. The screw recess is hexagon or star shaped to allow screw removal and insertion. The thread diameter of screw varies from 2.0 to 6.5mm, total length from 6 to 120mm.
Mechanism of Action	Internal Locking Plate and Screw Fixation System is a construct in which the screws are locked in the plate. The heads of the locking screws contain male threads while the holes in the plates contain female thread, this allows the screw head to be threaded into the plate. Various plate designs are available depending on specific anatomic locations, these may be larger or smaller, thicker or thinner as appropriate to various anatomic sites and the loads to which they will be subjected. The holes in the plate are designed for locking screws, or locking and non-locking screws combination to facilitate dynamic compression. By combining locking screw holes with compression screw slots in the shaft, the plate can be used as both a locking device and a fracture compression device. Internal Locking plate and screw Fixation systems do not disrupt the underlying cortical bone perfusion as much as conventional plates, which compress the plate to the cortical bone.
Materials	Titanium alloy (Ti-6Al-4V) ELI
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
Summary of intended use and technological characteristics	The Internal Locking plate and Screw 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 with only minor differences for the 3.5mm Round Hole Reconstruction

	Locking Plate indication, which is included in the predicate device's indication scope. The subject device and predicate devices are substantially equivalent with only minor differences in technological characteristics regarding: • Sterilization method • device material • Screw size These differences do not raise new questions of safety and effectiveness.
Non-clinical test	• Performance-bench test including: Single Cycle Bend Testing for bone plate per ASTM F382-17 Fatigue Property Testing for bone plate per ASTM F382-17 Torsional Properties Test for the screws per ASTM F543-17 Driving Torque Test for the screws per ASTM F543-17 Axial Pullout Strength Test for the screws per ASTM F543-17 Self-Tapping Performance Test for the screws per ASTM F543-17 •Reprocessing and sterilization Geasure completed manual cleaning and steam sterilization validation testing per the following guidance and standard document: FDA guidance document, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued March 17, 2015. AAMI TIR12: 2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers. AAMI TIR30: 2011/(R)2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. ISO 17665- 1:2006 Sterilization of health care products - Moist heat - Requirements for the development, validation, and routine control of sterilization process for medical devices. ISO 17665-2:2009 Sterilization of health care products - Moist heat - Part 2: Guidance of the application of ISO 17665-1. ISO 19227:2018 Implants for surgery - Cleanliness of orthopedic implants - General requirements.
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 Internal Locking Plate and Screw 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. These differences do not raise new questions of safety and effectiveness.
Conclusion	The non-clinical data demonstrates the Internal Locking Plate and Screw Fixation System is substantially equivalent to the predicate device.