February 10, 2025

Hebei Ruihe Medical Devices Co., Ltd.
Mengjia Chi
Regulatory Affairs Manager
No. 599 Qinling St, High-tech Industrial Development Zone
Shijiazhuang, Hebei 051430
China

Re: K240958
Trade/Device Name: Locking Plates and Screws Systems
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: April 7, 2024
Received: April 8, 2024

Dear Mengjia Chi:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240958

Device Name

Locking Plates and Screws Systems

Indications for Use *(Describe)*

Locking Plates and Screws Systems is intended to provide fixation during fractures, fusions, and osteotomies. Locking Plates and Screws Systems is indicated for the clavicle, and small bones including the metacarpals, wrist, metatarsals, tarsals and phalanges, and long bones including the radius, ulna, humerus, olecranon, fibula, femur, and tibia.

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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K240958
510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS
(As Required by 21 CFR 807.92)

1. Date Prepared [21 CFR 807.92(a)(1)]

02/10/2025

2. Submitter's Information [21 CFR 807.92(a)(1)]

Company Name:	Hebei Ruihe Medical Devices, Ltd.
Company Address:	No. 599 Qinling Street, High-tech Industrial Development Zone, Shijiazhuang, Hebei, 051430, China
Contact Person:	Ms. Meijia Chi
Phone:	86 18712837922
Email:	chimengjia@ruihe-med.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade Name: Locking Plates and Screws Systems

Device Common Name: Plate, Fixation, Bone

Device Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Device Classification: Class II

Classification Review Panel: Orthopedic Panel

Product Code: HRS

Regulation Number: 21CFR 888.3030 (Primary)

Device Classification Name: Smooth or threaded metallic bone fixation fastener

Common Name: Screw, Fixation, Bone

Device Classification: Class II

Classification Review Panel: Orthopedic Panel

Product Code: HWC

Regulation Number: 21CFR 888.3040

4. Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]

The identification of predicates within this submission is as follows:

Predicate Devices #1 (Primary):
510 (k) Number: K150009
Product Name: BaiDe® Locking Plate System
Submitter: Jiangsu BaiDe Medical Instrument Co. Ltd.

Predicate Devices #2:
510 (k) Number: K130108

Product Name: DOUBLE ENGINE BONE PLATE AND SCREW SYSTEMS
Submitter: Xiamen Double Engine Medical Material Co., Ltd.

5. Description of the Device [21 CFR 807.92(a)(4)]

Locking Plates and Screws Systems consists of metal locking plates, metal locking screws and non-locking metal screws, of which the metal locking plates offered are divided into ordinary type and limited-contact type. The locking plates are made of pure titanium material (TA3G per ASTM F67), and the metal bone screws are made of titanium-alloy (TC4 per ASTM F136). The product surface is color anodized, and the delivery state of the product is non-sterile.

6. Indications for Use [21 CFR 807.92(a)(5)]

Locking Plates and Screws Systems is intended to provide fixation during fractures, fusions, and osteotomies. Locking Plates and Screws Systems is indicated for the clavicle, and small bones including the metacarpals, wrist, metatarsals, tarsals and phalanges, and long bones including the radius, ulna, humerus, olecranon, fibula, femur, and tibia.

7. Technological Characteristic [21 CFR 807.92(a)(6)]

The Locking Plates and Screws Systems consists of metal locking plates including but not limited to: clavicle locking compression plates (67-147 mm length), proximal humerus locking compression plates (43-290 mm length), distal humerus compression plates (58-302mm length), proximal ulnar locking compression plate(50-216 mm), proximal radius locking compression plates (32-55.5 mm length), distal radius locking compression plates (40-240 mm length), proximal femoral locking compression plates (43-332 mm length), distal femoral locking compression plates (121-395 mm length), proximal tibial locking compression plates (69-400 mm length), distal tibial locking compression plates (64-288 mm length), distal fibula locking compression plates (62-233 mm length), locking compression plate (46-482 mm length), epiphyseal locking plates (28-411 mm length), achilles locking plates (41-76 mm length), navicular locking plates (58 mm length), straight locking compression plates (16.5-102 mm lengths), metatarsophalangeal locking plates (39-57 mm lengths), small L-shaped locking compression locking plates (32-71.8 mm length), small T-shaped locking compression plates (29.5-105.5 mm length), condylar locking compression plates (12-90 mm lengths), wrist fusion locking compression plates (117 mm length), as well as locking and non-locking screws (1.5-7.5 mm diameter, and 2-150 mm length).

8. Clinical Testing and Non-Clinical Testing

Clinical Testing	Not Applicable
Non-Clinical Testing	Mechanical Performance Testing was conducted according to ASTM F543 and ASTM F382. Driving torque, torsional strength, and axial pullout testing were conducted on the subject and predicate device screws according to ASTM F543. Four-point bend testing was conducted on the subject and predicate device plates according to ASTM F382.
	Sterilization Validation testing was conducted according to International Organization for Standardization (ISO) 17665-1: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical

	devices.
	Biocompatibility Testing was conducted according to ISO 10993 as well as the recommendations outlined in FDA guidance document, *"Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."*

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

9.1 Comparison between the subject device and the Safety and Performance Based Pathway

Table 1	Subject Device Locking Plates and Screws Systems	Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway and Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway	SE Discussion
Product Code	HRS	HRS	Same
Regulation No.	21 CFR 888.3030	21 CFR 888.3030	Same
Intended Use	Locking Plates and Screws Systems is intended to provide fixation during fractures, fusions, and osteotomies. Locking Plates and Screws Systems is indicated for the clavicle, and small bones including the metacarpals, wrist, metatarsals, tarsals and phalanges, and long bones including the radius, ulna, humerus, olecranon, fibula, femur, and tibia.	The fracture fixation plates that fall within the scope of this guidance document are intended for osteosynthesis (i.e., rigid fixation of opposing bone fragments for fracture fixation, osteotomy, or arthrodesis).	Note No.1, Note No.4

Material	TA3G conforms to ASTM F67 and TC4 conforms to ASTM F136	• ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) • ASTM F1472 Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400) • ASTM F1295 Standard Specification for Wrought Titanium-6 Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700) • ASTM F67 Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700) • ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673) • ASTM F139 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673) ASTM F1537 Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	Note No.2, Note No.5

Mechanical Performance	Test name: Static Four-Point Bending Methodology: FDA-recognized version of ASTM F382 Standard Specification and Test Method for Metallic Bone Plates. Test name: Driving torque, Torsional strength, Axial pullout testing Methodology: FDA-recognized version of ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws	Test name: Static Four-Point Bending Methodology: FDA-recognized version of ASTM F382 Standard Specification and Test Method for Metallic Bone Plates.	Note No.6
Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized) Validation	Test name: Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized) Methodology: International Organization for Standardization (ISO) 17665-1 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices	Test name: Sterilization (devices labeled as sterile) and Reprocessing (end-user sterilized) Methodology: FDA currently-recognized versions of the following consensus standards (as applicable): International Organization for Standardization (ISO) 17665-1 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices • ISO 11135-1 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices • ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a	Note No.7

		sterilization process for medical devices Contains Nonbinding Recommendations: • ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems • ISO 11607-2 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	
Biocompatibility Evaluation	Test name: Cytotoxicity test Methodology: Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Test name: Biocompatibility endpoints Methodology: Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Same

9.2 Comparison of test standards for the subject device and the Predicate Device

Table 2	Subject Device	Predicate Device 1	SE Discussion
Device Name	Locking Plates and Screws Systems	BaiDe® Locking Plate System	N/A
ASTM F382	Yes	Yes	Same, Note No.6
ASTM F543	Yes	Yes	Same, Note No.6

Table 3	Subject Device	Predicate Device 2	SE Discussion
Device Name	Locking Plates and Screws Systems	DOUBLE ENGINE BONE PLATE AND SCREW SYSTEMS	N/A
ASTM F382	Yes	Yes	Same, Note No.6
ASTM F543	Yes	Yes	Same, Note No.6

9.3 Justification

Note ID	Justification
Note No.1	Subject Device lists its indications in detail, with consistent basic uses and can be regarded as substantially equivalent.
Note No.2	The materials used in the plates are within the range of the SPBP path list material and are therefore considered substantially equivalent.
Note No.3	The plate is within the SPBP path enumeration range and therefore considered

	substantially equivalent.
Note No.4	Subject Device lists its indications in detail, which is consistent with the intended uses outlined in the SPBP guidance document and predicate devices, and therefore can be regarded as substantially equivalent.
Note No.5	The materials used for the bone screws are within the SPBP path enumerated material range and are therefore considered substantially equivalent.
Note No.6	Using the internationally recognized standard ASTM F543 and ASTM F832, test results meet the SPBP path requirements or are similar to the results of the predicate device, therefore demonstrating that the subject device mechanical performance results are as safe and effective as the predicate devices.
Note No.7	The source criteria for the recommended sterilization parameters for the subject device are within the SPBP path listing criteria and are therefore considered substantially equivalent.

10. Conclusion [21 CFR 807.92(b)(3)]

The subject device has same intended use, similar performance, equivalent testing standards, and all technological characteristics are similar to the predicate device or Safety and Performance Based Pathway Criteria, indicate that the proposed device is as safe and effective as the predicate device.

Any differences between the proposed subject device and the predicate device or Safety and Performance Based Pathway Criteria do not affect the intended use, technological characteristics, safety and/or effectiveness. Therefore, the subject device is as safe and effective as the predicate device identified.