June 11, 2025

Bonebridge AG
Michelle Gumpelmayer
Head of QM&RA
Bahnhofstrasse 11
Zug, Zug 6300
Switzerland

Re: K250933
Trade/Device Name: LORRAINE 2.5/3.5mm Distal Humerus 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: April 16, 2025
Received: April 16, 2025

Dear Ms. Gumpelmayer:

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,

Thomas Mcnamara -S

For: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250933

Please provide the device trade name(s).

LORRAINE 2.5/3.5mm Distal Humerus System

Please provide your Indications for Use below.

The LORRAINE 2.5/3.5mm Distal Humerus System is indicated for intra-articular or extra-articular fractures of the distal humerus, supracondylar fractures, osteotomies, and non-unions. Longer plates may be used for distal humerus fractures with diaphyseal extension.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

In accordance with 21 CFR 807.92 the following information is provided for the Bonebridge Osteosynthesis Plating System.

ADMINISTRATIVE INFORMATION

Date prepared	June 11, 2025
Submitter	Bonebridge AG Bahnhofstrasse 11 6300 Zug Switzerland
Official Contact	Michelle Gumpelmayer Head of QM&RA, Bonebridge AG Phone: +41 76 731 07 32 Email michelle.gumpelmayer@bonebridge.ch
Alternative Contact	Alexander Häusler COO, Bonebridge AG Phone: +41 79 660 81 42 Email alexander.haeusler@bonebridge.ch

DEVICE NAME AND CLASSIFICATION

Trade name:	LORRAINE 2.5/3.5mm Distal Humerus System
Common name:	Plate, Fixation, Bone Screw, Fixation, Bone
Regulation number:	21 CFR 888.3030 (Primary) 21 CFR 888.3040
Classification name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Regulatory class:	Class II
Product Code:	HRS HWC

PREDICATE DEVICES

Primary predicate device: Bonebridge Osteosynthesis Plating System
K231292 LORRAINE 3.5mm Distal Humerus System

Subject Device:	Additional predicate devices:
LORRAINE 2.5/3.5mm Distal Humerus System	K120070 Synthes Variable Angle LCP Elbow System / Distal Humerus Plates K101056 VariAx Elbow System / Distal Humerus Plates K082807 Synthes (USA) 3.5 and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indication
Bonebridge Bone Screws	K203002, K213864 Bonebridge Bone Screws

INDICATIONS FOR USE

The LORRAINE 2.5/3.5mm Distal Humerus System is indicated for intra-articular or extra-articular fractures of the distal humerus, supracondylar fractures, osteotomies, and non-unions. Longer plates may be used for distal humerus fractures with diaphyseal extension.

DEVICE DESCRIPTION

The Bonebridge Osteosynthesis Plating System is intended for treating fractures of various bones. It consists of plates, locking and non-locking screws for fixation and corresponding instruments. The plating system is further subdivided into variants/types based on the anatomical location of the fracture. The subject LORRAINE 2.5/3.5mm Distal Humerus System is a variant of the Bonebridge Osteosynthesis Plating System.

The plates are primarily manufactured from stainless steel (ISO 5832-1, ASTM F138, or ASTM F139) and include Titanium Inlay Clips (TICs) made from pure titanium (ASTM F67 or ISO 5832-2). The screws are manufactured entirely from stainless steel (ISO 5832-1, ASTM F138, or ASTM F139).
All materials used are biocompatible, corrosion-resistant and nontoxic in a biological environment. Surgical instruments are made of stainless steel (ASTM F899, ISO 7153-1, ISO 5832-1, and ASTM F138/139), medical grade PEEK, medical grade EPDM terpolymer, or medical grade silicone. All plates are sterilized with gamma irradiation and delivered sterile. Screws and instruments are delivered non-sterile. Devices supplied in a non-sterile condition must be cleaned and steam sterilized prior to surgical use. Non-clinical testing has demonstrated the implants are MR Conditional.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

The subject devices and the predicate devices have the same intended use, similar indications for use, and technological characteristics. The subject and predicate devices are all fabricated from the same materials and share the same design characteristics, including plate screw holes to accommodate locking and non-locking screws. The subject and predicate devices encompass the same range of physical dimensions, and the subject device is compatible with screws from the primary predicate device. The subject and predicate devices are sterilized by the standard methods.

SUMMARY OF NON-CLINICAL TESTS

Sterilization validation:	Gamma irradiation: The minimal dose of 25kGy is validated using VDmax25 method as described in ISO 11137-2 and confirmed a Sterility Assurance Level SAL of 10^{-6}. Steam sterilization: Cleaning and sterilization procedures have been successfully validated in accordance with ISO 17664 and ISO 17665-1 at 132°C (270F) for 4 minutes and 20 min drying time.	Pass
Packaging validation:	Validation of the sterile packaging has been successfully performed in accordance with ISO 11607 1/2 and ASTM F1980. Furthermore, a transport simulation was conducted according ISTA 2A followed by these packaging verification tests: • Dye-Penetration, ASTM F1929 • Visual inspection, ASTM F1886/1886M • Seal strength, ASTM F88/F88M • Microbial barrier testing, DIN 58953-6, Chapter 2.14	Pass
Biocompatibility:	Biological Evaluation and toxicological risk assessment to evaluate the device's biological safety for the intended use, in accordance with ISO 10993-series and FDA guidance.	Pass
Mechanical testing:	Static and dynamic comparative testing was performed for each subject plate variant, including statistical analysis and comparison to the respective predicate devices. Substantial equivalence of each Bonebridge subject plate variant to the corresponding predicate devices was demonstrated with respect to maximum force, yield strength and construct stiffness (static test) and maximum force for a given number of cycles (dynamic test). All predefined acceptance criteria were successfully met, demonstrating that the mechanical performance of each subject plate variant is substantially equivalent to the corresponding predicate devices.	Pass
MRI safety:	The Bonebridge Osteosynthesis Plating System is MR conditional considering local SAR based on the following tests • Assessment of displacement force and torque effects in the main static magnetic field at 3Tesla. Additionally, the expected magnetic force in a stronger magnetic field gradient of 30T/m was extrapolated. (According to ASTM F2052-21 and ASTM F2213-17) • Assessment of heating effects due to the RF-field during MR scans at 1.5Tesla and 3Tesla according to ASTM F2182-19 • Assessment of image artifacts at 3Tesla according to ASTM F2119-24 The tested implant and associated product family can be claimed as MR conditional.	Pass

CONCLUSION

The subject LORRAINE 2.5/3.5mm Distal Humerus System has the same indications, intended use, target populations, technological characteristics, and materials as the primary predicate device. Non-clinical testing demonstrated that the performance of the proposed devices is substantially equivalent to the predicate devices.