August 23, 2024

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

Re: K240318
Trade/Device Name: SITTER 3.5mm Versatile 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
Dated: July 29, 2024
Received: July 30, 2024

Dear Michelle 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.

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, MS
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)*

K240318

Device Name

SITTER 3.5mm Versatile System

Indications for Use *(Describe)*

The SITTER 3.5mm Versatile System is indicated for fixation of fractures, osteotomies and nonunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula in adult patients with normal or osteopenic bone.

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

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

ADMINISTRATIVE INFORMATION

Date prepared	July 29, 2024
Submission type:	Traditional 510(k)
Purpose of 510(k):	Modification of currently cleared device K231292 Introduction of an additional plating system SITTER 3.5mm Versatile System Announcement of minor modifications to the device since the last clearance (K231292)
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
US agent	Richard Robel, confinis corporation Email: usagent@confinis.com

DEVICE NAME AND CLASSIFICATION

Trade name:	SITTER 3.5mm Versatile System (Bonebridge Osteosynthesis Plating System)
Variants, types:	TRIFT 3.5mm 1/3 Tubular System SALGINA 2.5mm Volar Distal Radius System CASCELLA 3.5mm Superior Clavicle System TAMINA 3.5mm Proximal Humerus System POYA 3.5mm Lateral Proximal Tibia System POYA 3.5mm Posteromedial Tibia System DALVAZZA 2.5mm Distal Ulna System LEPORELLO 3.5mm Olecranon System LORRAINE 3.5mm Distal Humerus System SITTER 3.5mm Versatile System

Common name:	Plate, Fixation, Bone
Regulation number:	21 CFR 888.3030
Classification name:	Single/multiple component metallic bone fixation appliances and accessories
Regulatory class:	Class II
Product Code:	HRS

PREDICATE DEVICES

Primary predicate device:	Bonebridge Osteosynthesis Plating System (K231292) TAMINA 3.5mm Proximal Humerus System
Additional predicate devices:	
SITTER 3.5mm Versatile System	K082807 Synthes (USA) 3.5 mm Locking Compression Plate (LCP) System with Expanded Indications

INDICATIONS FOR USE

SITTER 3.5mm Versatile System:

The SITTER 3.5mm Versatile System is indicated for fixation of fractures, osteotomies and nonunions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula in adult patients with normal or osteopenic bone.

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. Plates and screws are made of stainless steel (ISO 5832-1 or ASTM F138 or ASTM F139) or pure titanium (ASTM F67 or ISO 5832-2). 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 devices are MR Conditional.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

The subject device and the predicate devices have the same intended use, similar indications for use, and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar 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 predicate devices. The subject and predicate devices are sterilized by the standard methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

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. Tests performed: Chemical Characterization, Cytotoxicity and LAL Testing	Pass
Mechanical testing:	Plates: Static and dynamic comparative testing has been performed and included statistical analysis and comparative testing to the predicate device. Non-inferiority of the Bonebridge device compared to the predicate device with regard to maximum force (static test) and maximum force for a given number of cycles (dynamic test). The predefined acceptance criteria were successfully met. Design verification was successfully completed and included compatibility of implants and instruments as well as assessment of anatomical shape and appearance.	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 of the implant in the main static magnetic field at 3.0Tesla according to ASTM F2052-21 and ASTM F2213-17. Additionally, the expected magnetic force in a stronger magnetic field gradient of 30T/m was extrapolated. • Assessment of heating effects due to the RF-field during MR scans at 1.5Tesla and 3Tesla according to ASTM F2182-19e1. • Assessment of image artifacts at 3Tesla according to ASTM F2119-07 (2013) The tested implant and associated product family can be claimed as MR conditional.	Pass

SUMMARY OF CLINICAL AND USABILITY TESTS

Based on a clinical evaluation including literature review and the results of verification and validation activities it has been concluded that clinical investigations were not required. The summative usability evaluation according to IEC 62366-1 shows that the Bonebridge Osteosynthesis Plating System there are no significant usability issues due to the study acceptance criteria of the primary objectives prior Application/ Usability Risk Assessment update. Therefore, the summative usability evaluation studies of the Bonebridge Osteosynthesis Plating System are considered successful. The study participants were able to use the products safely and effectively.

CONCLUSION

The subject Bonebridge Osteosynthesis Plating System has similar indications, intended use, target populations, technological characteristics, and materials as the predicate devices. Non-clinical testing demonstrated that the performance of the proposed devices is equivalent to the predicate devices.