October 5, 2021

Bonebridge AG
℅ Sandra Soniec
Managing Director
meditec Consulting GmbH
Obermoosstrasse 23
Boll, Berne 3067
Switzerland

Re: K203002
Trade/Device Name: Bonebridge Osteosynthesis Plating 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: September 3, 2021
Received: September 7, 2021

Dear Sandra Soniec:

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,

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

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)*
K203002

Device Name
Bonebridge Osteosynthesis Plating System

Indications for Use *(Describe)*

The TRIFT 3.5mm 1/3 Tubular Plate is indicated for:
• Treatment of smaller fractures of long bones such as humerus, fibula, and ulna

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

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

ADMINISTRATIVE INFORMATION

Date prepared	October 5, 2021
Submission type:	Traditional 510(k)
Purpose of 510(k):	Introduction of a new osteosynthesis plating system
Submitter	Bonebridge AG Bahnhofstrasse 11 6300 Zug Switzerland
Official Contact	Christof Gerber M.D. CEO, Bonebridge AG
Alternative Contact	Sandra Soniec Senior consultant, meditec Consulting GmbH Phone: +41 31 535 3193 Email soniec@meditec-consulting.ch
US agent	Viky Verna, confinis corporation Email: viky.verna@confinis.com

DEVICE NAME AND CLASSIFICATION

Trade name:	Bonebridge Osteosynthesis Plating System
Variants, types:	TRIFT 3.5mm 1/3 Tubular 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 DEVICE

Bonebridge Osteosythesis Plating System	Primary predicate device
TRIFT 3.5mm 1/3 Tubular System	SYNTHES one-third tubular plate 3.5mm K011335 SYNTHS ONE-THIRD TUBULAR DCL PLATE

INDICATIONS FOR USE

The TRIFT 3.5mm 1/3 Tubular Plate is indicated for:

- Treatment of smaller fractures of long bones such as humerus, fibula, and ulna

DEVICE DESCRITION

The Bonebridge Osteosynthesis Plating System is intended for treating fractures of various bones. It consists of plates and non-locking screws for fixation and corresponding instruments.
Plates and screws are made of stainless steel (ISO 5832-1 or 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 (ISO 5832-1 or ASTM F138 or ASTM F899), 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.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

The subject device and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate device are all fabricated from the same or similar materials and share similar design characteristics, including plate screw holes to accommodate 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 device. The subject and predicate device are sterilized by the standard methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

SUMMARY OF PERFORMANCE DATA

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.

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

Biocompatibility: A biological assessment has been performed in accordance with ISO 10993-1.

Mechanical testing: Plates: Static and dynamic testing has been performed and included statistical analysis and comparative testing to the predicate devices. The predefined acceptance criteria were successfully met.

Screws: Tested successfully in accordance with ASTM F543: Standard Specification and Test Methods for Metallic Medical Bone Screws an includes comparative testing to predicate devices.

Design verification was successfully completed and included compatibility of implants and instruments as well as assessment of anatomical shape and appearance.

MRI safety: The Bonebridge Osteosythesis 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 F2052-15 and ASTM F2213-17)
- Assessment of heating effects due to the RF-field during MR scans at 1.5Tesla and 3Tesla according to ASTM F2182-11a
- Assessment of image artifacts at 3Tesla according to ASTM F2119-07 (2013)

Usability:	Summative usability evaluation studies in accordance with IEC 62366-1 support that 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 Osteosythesis Plating System are considered as successful. The study participants were able to use the products safely and effectively.
Clinical evaluation:	Based on the results of the literature review and the results of verification and validation activities it has been concluded that clinical investigations are not required, since surgical technique, device design and material match established interventions for the relevant indications.

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.