



April 24, 2026

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

Re: K260228

Trade/Device Name: POYA 3.5mm Medial Proximal Tibia 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: January 26, 2026

Received: January 26, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto: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

# 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.

K260228

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Please provide the device trade name(s).

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POYA 3.5mm Medial Proximal Tibia System

Please provide your Indications for Use below.

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The POYA 3.5mm Medial Proximal Tibia System is intended for adult patients and 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 de-pression fractures of the medial tibia plateau. Also, for use in the fixation of osteo-penic bone and fixation of nonunions and malunions of the medial proximal tibia. Additionally, the longer plates are indicated for fractures extending to the tibial shaft.

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

Prescription Use (21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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**K260228**  
**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	January 26, 2026
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 <a href="mailto:michelle.gumpelmayer@bonebridge.ch">michelle.gumpelmayer@bonebridge.ch</a>
Alternative Contact	Alexander Häusler COO, Bonebridge AG Phone: +41 79 660 81 42 Email <a href="mailto:alexander.haeusler@bonebridge.ch">alexander.haeusler@bonebridge.ch</a>

**DEVICE NAME AND CLASSIFICATION**

Trade name:	POYA 3.5mm Medial Proximal Tibia 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  
K242399 POYA 3.5mm Medial Proximal Tibia System

Subject Device:

Additional predicate devices:

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POYA 3.5mm Medial Proximal Tibia  
System

K231292 POYA 3.5mm Lateral  
Proximal Tibia Plates

K032269 Synthes (USA) 3.5 LCP  
Medial Proximal Tibia Plates

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## **INDICATIONS FOR USE**

The POYA 3.5mm Medial Proximal Tibia System is intended for adult patients and 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. Additionally, the longer plates are indicated for fractures extending to the tibial shaft.

## **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 device POYA 3.5mm Medial Proximal Tibia 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 device and the predicate devices have the same intended use, and similar indications for use, technological characteristics, and materials.

The subject and predicate devices 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 standard methods.

## SUMMARY OF NON-CLINICAL TESTS

Sterilization validation:	<p>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 <math>10^{-6}</math>.</p> <p>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.</p>	Pass
Packaging validation:	<p>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:</p> <ul style="list-style-type: none"><li>• Dye-Penetration, ASTM F1929</li><li>• Visual inspection, ASTM F1886/1886M</li><li>• Seal strength, ASTM F88/F88M</li><li>• Microbial barrier testing, DIN 58953-6, Chapter 2.14</li></ul>	Pass
Biocompatibility:	<p>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.</p>	Pass
Mechanical testing:	<p>Static and dynamic comparative testing was performed for the worst-case of the subject plate variant in the previous submissions, 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) or with respect to static four-point bending strength and bending structural stiffness. All predefined acceptance criteria remain successfully met, demonstrating that the mechanical performance of each subject plate variant is substantially equivalent to the corresponding predicate devices.</p>	Pass
MRI safety:	<p>The Bonebridge Osteosynthesis Plating System is MR conditional considering local SAR based on the following tests</p> <ul style="list-style-type: none"><li>• 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)</li><li>• Assessment of heating effects due to the RF-field during MR scans at 1.5Tesla and 3Tesla according to ASTM F2182-19</li><li>• Assessment of image artifacts at 3Tesla according to ASTM F2119-24</li></ul> <p>The tested implant and associated product family can be claimed as MR conditional.</p>	Pass

**CONCLUSION**

The subject POYA 3.5mm Medial Proximal Tibia System, has the same intended use and similar indications for use, technological characteristics, and materials as the respective predicate devices. Non-clinical performance testing demonstrated that the subject devices are substantially equivalent to the predicate devices.