



April 22, 2022

Biomet Microfixation  
% Christine Scifert  
Principal Consultant  
MRC Global, LLC  
9085 E Mineral Circle, Suite 110  
Centennial, Colorado 80112

Re: K212608

Trade/Device Name: Biomet Microfixation RibFix Blu Thoracic Fixation 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: August 16, 2021

Received: August 17, 2021

Dear Christine Scifert:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: 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

## Indications for Use

510(k) Number (if known)

K212608

Device Name

Biomet Microfixation RibFix Blu Thoracic Fixation System

Indications for Use (Describe)

The Biomet Microfixation RibFix Blu Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, rib fractures associated with flail chest, or planned osteotomies. The system may be used in normal and poor bone to promote union.

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.

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## 510(k) Summary

### *Biomet Microfixation RibFix Blu Thoracic Fixation System*

April 22, 2022

**Company:** Biomet Microfixation  
1520 Tradeport Drive  
Jacksonville, FL 32218

**Primary Contact:** Christine Scifert  
Christine.scifert@askmrcglobal.com  
Phone: (901) 831-8053

**Company Contact:** Lauren Jasper  
lauren.jasper@zimmerbiomet.com  
Phone: (904) 741-9259

**Trade Name:** Biomet Microfixation RibFix Blu Thoracic Fixation System

**Common Name:** Bone Plate and Bone Screw

**Classification:** Class II

**Regulation Number:** 21 CFR 888.3030 and 888.3040

**Panel:** 87- Orthopedic

**Product Code:** HRS and HWC

#### **Device Description:**

The Biomet Microfixation RibFix Blu Thoracic Fixation System is composed of metallic locking bone plates and locking screws that provide rigid fixation to fractures and osteotomies of the chest wall. These implants are available in multiple sizes and manufactured from Commercially Pure Titanium and Titanium Alloy (Ti-6Al-4V).

#### **Indications for Use:**

The Biomet Microfixation RibFix Blu Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, rib fractures associated with flail chest, or planned osteotomies. The system may be used in normal and poor bone to promote union.

#### **Predicate Device:**

K162974, Biomet Microfixation RibFix Blu Thoracic Fixation System

The similarities of the subject devices to the predicate devices are as follows:

- The contraindications are identical to that of the predicate device.
- The design of the subject devices is equivalent to the predicate devices.
- The sterilization method (steam sterilization) of the subject devices is identical to the predicate devices.
- The materials of the subject devices are identical to the predicate devices.

The differences of the subject devices as compared to the predicate devices are as follows:

- Update indications for use to include fixation of “rib fractures associated with flail chest.”
- Update package insert to include MR conditional parameters and symbol.
- Update outer package label to include MR conditional symbol.

**Non-Clinical Performance Data:** The following non-clinical testing has been performed and met all established acceptance criteria:

- Magnetic Resonance Testing per ASTM F2182-11
- Physiologic Loading Thoracic Testing
- Thoracic Fatigue Testing
- Thoracic Failure Testing

**Clinical Performance Data:** Clinical testing was not necessary for the determination of substantial equivalence.

**Sterilization Information:** There have been no changes to the sterilization. The implants and instruments are provided non-sterile to be sterilized by steam at the end user facility.

**Substantial Equivalence:** The proposed device has similar indications for use as the predicate devices. The submission demonstrates that (1) any differences in technological characteristics of the predicates do not raise any new questions of safety and efficacy and (2) the proposed device is at least as safe and effective as the predicates. It is concluded that the information included in this summary supports substantial equivalence.