January 28, 2021

Biomet Micofixation
Lauren Jasper
Regulatory Affairs Manager
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K203474
Trade/Device Name: Biomet Microfixation RibFix Advantage 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, HTN
Dated: November 24, 2020
Received: November 25, 2020

Dear Lauren Jasper:

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, MPH
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)*

K203474

Device Name

Biomet MicrofixationR ibFix Advantage System

Indications for Use *(Describe)*

TheR ibFix Advantage System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic 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

Prepared January 28, 2021

Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Contact: Lauren Jasper, Regulatory Affairs Manager
lauren.jasper@zimmerbiomet.com
Telephone: (904) 741-9259

Device Name: Biomet Microfixation RibFix Advantage System

Device Classification:

Product Code	Classification Name	Device Classification	Regulation Number	Regulation Description
HRS (Primary)	Plate, Fixation, Bone	2	888.3030	Single/multiple component metallic bone fixation appliances and accessories
HWC	Screw, Fixation, Bone	2	888.3040	Smooth or threaded metallic bone fixation fastener
HTN	Washer, Bolt Nut	2	888.3030	Single/multiple component metallic bone fixation appliances and accessories.

Indications for Use: The RibFix Advantage System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

Contraindications: The RibFix Advantage system is contraindicated for:

1. Use in patients with latent or active infection, sepsis, and/or device material sensitivity.
2. Use in patients who are unwilling or incapable of following postoperative care instructions.
3. This device is not intended for locking post attachment or fixation to the clavicle or spine.
4. This device is not intended for highly comminuted fractures.

Device Description: The RibFix Advantage System consists of bridges (with locking posts) and locking caps for the thoracoscopic fixation and stabilization of ribs. These implants are manufactured from commercially pure titanium (per ASTM F67) and titanium alloys (Ti-6Al-7Nb

per ASTM F1295 and Ti-6Al-4V per ASTM F136 or ASTM F1472). The system is comprised of the following implants:

- Titanium alloy RibFix Advantage Bridge with threaded locking posts
- Commercially pure titanium locking caps
- Commercially pure titanium washers (optional)

When fully assembled, the bridge is placed on the underside of the rib, the threaded locking posts extends through pre-drilled holes in the rib, and the locking caps are fixed to the locking post on the anterior side of the rib. Washers may be placed on the posts prior to assembling with locking caps. The combined threaded locking post/locking cap provides for fixation of the bridge. The devices are sold non-sterile and intended to be sterilized by the user prior to implantation. The system also includes reusable instrumentation to aid in implantation of the devices.

The design, materials, sterilization method, and indications for use are identical between the subject device and the predicate device.

Substantial Equivalence:
Primary Predicate Device: K183317, AdvantageRib System

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

- The indications for use 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 package insert to include MR conditional parameters and symbol
- Update outer package label to include MR conditional symbol
- Update cleaning instructions for the processing of reusable instruments and new/uncompromised implants.
- Add additional sterilization parameters applicable for other geographic locations.
- Revise the contraindications statement.

Additional Reference Devices:
K162974, Biomet Microfixation RibFix Blu Thoracic Fixation System
K163007, Biomet Microfixation SternaLock 360 Sternal Closure Fixation System
The similarities of the subject devices to these predicate devices are as follows:

- The cleaning and sterilization instructions provided in the package insert are identical.

Non-Clinical Performance Data: The following nonclinical tests were submitted and relied on in this premarket notification submission for a determination of substantial equivalence. Testing identified in this summary has all passed acceptance criteria established by the predicate device where applicable.

MR Safety Evaluation following standards listed below:

- ASTM F2052-15, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"
- ASTM F2213-17, "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"
- ASTM F2182-11a, "Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging"
- ASTM F2119-07 (Reapproved 2013), "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"

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

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

Conclusion: The proposed device has identical 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.