May 17, 2022

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

Re: K212782
Trade/Device Name: Biomet Microfixation SternaLock® 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: August 31, 2021
Received: September 1, 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) 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)*
K212782

Device Name
Biomet Microfixation SternaLock® System

Indications for Use *(Describe)*
The Biomet Microfixation SternaLock® System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation SternaLock® System is intended for use in patients with normal and poor bone quality.

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 SternaLock® System

May 16, 2022

Company: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Primary Contact: Christine Scifert
Christine.Scifert@askmrcglobal.com
Phone: 901-831-8053

Company Contact: Mark Wladkowski
mark.wladkowski@zimmerbiomet.com
Phone: (904) 362-3940

Trade Name: Biomet Microfixation SternaLock® System

Common Name: Bone Plate

Classification: Class II

Regulation Number: 21 CFR 888.3030

Panel: 87- Orthopedic

Product Code: HRS

Device Description:

The Biomet Microfixation SternaLock® System is composed of metallic locking bone plates and locking screws that provide stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. 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 SternaLock® System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion. The Biomet Microfixation SternaLock® System is intended for use in patients with normal and poor bone quality.

Predicate Device:
K161896, Biomet Microfixation Sternal Closure System
The similarities of the subject devices to the predicate devices are as follows:

- The design of the subject devices is equivalent to the predicate device.
- The indications and contraindications of the subject device are identical to the predicate device.
- 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.
- Minor updates to the package insert content not related to product indications.

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

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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.