January 7, 2022

Biomet Micofixation
℅ Danielle Besal
Principal Consultant
MRC Global, LLC
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K212841
Trade/Device Name: Pectus Blu Support Bar 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: December 1, 2021
Received: December 2, 2021

Dear Danielle Besal:

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
DHT6B: 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)*
K212841

Device Name
Pectus Blu Support Bar System

Indications for Use *(Describe)*
The Pectus Blu system is indicated for the treatment of Pectus Excavatum and other sternal deformities. It is intended to be used in pediatric (children and adolescents) and adult populations.

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
Pectus Blu Support Bar System
December 1, 2021

Company: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Primary Contact: Danielle Besal
Danielle.Besal@askmrcglobal.com
Phone: (901) 827-8670

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

Trade Name: Pectus Blu Support Bar System
Common Name: Plate, Fixation, Bone
Classification: Class II
Regulation Number: 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Panel: 87- Orthopedic
Product Code: HRS: Plate, Fixation, Bone

Device Description:
The Biomet Microfixation Pectus Blu Support Bar and Stabilizers are surgical implants intended to aid treatment of Pectus Excavatum deformity in adults and pediatric patients (children and adolescents) for which the rib cage across the sternum measures 7 inches (17.78 centimeters) or larger. The Pectus Blu Support Bar provides the surgeon with a means to reposition bony structures (sternum, breastbone) by applying internal force outwardly eliminating the funnel shape deformity. Recommended implantation time is 2-3 years, but may vary based on surgeon preference and patient. These devices are offered in a generic pre-bent shape that can be further shaped intraoperatively. These devices are intended to be used in professional healthcare facilities.

The Pectus Blu Support Bar and Stabilizers are made of titanium alloy (ASTM F136) and provided non-sterile for sterilization by the end user.

Indications for Use:
The Pectus Blu system is indicated for the treatment of Pectus Excavatum and other sternal deformities. It is intended to be used in pediatric (children and adolescents) and adult populations.

Predicate Device:
K061384: Biomet Microfixation Lorenz Pectus Support Bar System

The similarities of the subject devices to the predicate devices are as follows:
- Intended use
- Support bar geometry and sizing
- Materials of construction
- Sterilization method

The differences of the subject devices compared to the predicate devices are as follows:
- Modified design of stabilizer that eliminates the need for wiring

- MR conditional labeling

Performance Testing:
Mechanical testing was performed according to ASTM F382-17 and all tests confirmed that the product met the predetermined acceptance criteria. MR compatibility testing was performed in compliance with the following standards: ASTM F2052-15, ASTM F2213-17, ASTM F2182-19, and ASTM F2119-07. The results of the testing showed the devices are MR Conditional, which is reflected in the product labeling. Biological safety risk assessments in compliance with ISO 10993-1:2018 were completed on the subject devices and concluded the devices are biocompatible and appropriate for their intended use. Clinical data was not required for the determination of substantial equivalence.

Substantial Equivalence:
The subject devices are substantially equivalent to the predicate Lorenz Pectus Support Bar System (K061384). The subject components are similar in indications, sizing and geometry, technological characteristics, and materials to the predicates as described in this premarket notification. Any differences in technological characteristics between the subject and predicate devices do not raise any new questions of safety and effectiveness and the subject device is at least as safe and effective as the predicate. It is concluded that the information in this 510(k) supports substantial equivalence of the devices.