September 19, 2024

Biomet Microfixation
Smeet Doshi
Regulatory Affairs Senior Specialist
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K241709
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: August 16, 2024
Received: August 16, 2024

Dear Smeet Doshi:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher Ferreira -S

Christopher Ferreira, M.S.
Assistant Director, Biomedical Engineer
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241709

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.

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510(k) Summary

Pectus Blu Support Bar System

1. **Date Prepared:** September 09, 2024

2. **Sponsor Name and Address:**

Biomet Microfixation
1520 Tradeport Drive
Jacksonville FL 32218
Phone: 213-910-4996
Contact: Smeet Doshi, Regulatory Affairs Senior Specialist, Regulatory Affairs

3. **Device Name:**

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

4. **Predicate Device:**

Trade Name: Pectus Blu Support Bar System
Common Name: Plate, Fixation, Bone
Risk Classification: Class II
Product Code: HRS
Regulation Number and Description: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
510(K) Numbers: K212841

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

- Indications for Use/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:

- Line extension with added stabilizer (Pectus Blu TruLink™ Stabilizers) to further aid in implantation of multiple bars.

5. Device Description:

The Pectus Blu Support Bar and Stabilizers (including Pectus Blu TruLink™ 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.

6. 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.

7. Technological Characteristics:

The proposed modification does not change the fundamental design, operating principles, and the intended/indications for use of Pectus Blu Support Bar System. Therefore, the technological characteristics of the modified device remain substantially equivalent to that of the predicate device (K212841). The new Pectus Blu TruLink Stabilizer, is an addition to the current stabilizer, is used to further aid in implantation of multiple bars. The Pectus Blu Support Bar System which includes the TruLink Stabilizer is substantially equivalent to the legally marketed predicate device Pectus Blu Support Bar System (K212841) in that these devices are identical in use, utilize identical materials, and operate using the same fundamental design principles.

8. Performance Data:

Performance data for all modifications are provided in the Verification and Validation attachments to the 510(k). All modifications were tested to standardized or equivalent test methods as established in the predicate device 510(k) K212841.

9. Conclusions:

The Pectus Blu Support Bar System with modification to include the Pectus Blu TruLink Stabilizers is determined to remain substantially equivalent to the FDA-cleared (per K212841) Pectus Blu Support Bar System (the predicate device). 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.