



June 2, 2026

Biomet Microfixation
% Danielle Besal
Principal Consultant
MRC Global, LLC
9160 Hwy. 64, Suite 12
P.O. Box 330
Lakeland, Tennessee 38002

Re: K261002

Trade/Device Name: Pectus Blu 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: April 9, 2026
Received: April 10, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261002

?

Please provide the device trade name(s).

?

Pectus Blu System

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) #: K261002

510(k) Summary

Prepared on: 2026-04-09

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Biomet Microfixation
Applicant Address	1520 Tradeport Dr Jacksonville FL 32218 United States
Applicant Contact Telephone	904-741-4400
Applicant Contact	Jose Ponce
Applicant Contact Email	jose.ponce@zimmerbiomet.com
Correspondent Name	MRC Global, LLC
Correspondent Address	9160 HWY 64, STE 12 PO BOX 330 Lakeland TN 38002 United States
Correspondent Contact Telephone	9018278670
Correspondent Contact	Danielle Besal
Correspondent Contact Email	danielle.besal@askmrcglobal.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Pectus Blu System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241709	Pectus Blu Support Bar System	HRS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The 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). 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.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are identical to those of the predicate.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The addition of new stabilizer bars and the labeling change to allow implantation of the support bars in a crossed orientation do not change the fundamental design, operating principle, or intended use of the Pectus Blu System. The new stabilizer bars are made from the identical material and size range to the predicate device, but have a slightly different geometry featuring a barbell shape. The subject labeling change allows the surgeon the option of implanting the support bars in a crossed orientation (when multiple bars are used) versus a parallel support bar orientation in the predicate labeling. Both the subject and predicate devices allow implantation of multiple support bars and performance testing on the crossed bar configuration has demonstrated equivalency to that of the predicate parallel orientation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Construct bending fatigue testing and MR compatibility evaluation were successfully completed on the subject device and results demonstrated substantial equivalence to the predicate device.