December 19, 2025

GM Dos Reis Industria e Comercio
Guilherme Esteves Pontes
Senior Regulatory Affairs Analyst
Avenida Pierre Simon de LaPlace, 600
Campinas, SP 13069320
Brazil

Re: K251050
Trade/Device Name: Pectus Versa 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 1, 2025
Received: April 3, 2025

Dear Guilherme Esteves Pontes:

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, MS.
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.	K251050

Please provide the device trade name(s).

Pectus Versa System

Please provide your Indications for Use below.

The Pectus Versa System is indicated for the treatment of Pectus Excavatum and other anterior chest wall deformities in adult and pediatric patients (children and adolescents).

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)

Section 5 - 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter:

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Date prepared: December 19, 2025

II. Device Name:

Trade Name:	Pectus Versa System
Common Name:	Plate, fixation, bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Device Class:	II
Product Codes:	HRS
Regulation Number:	21 CFR 888.3030

III. Predicate Devices:

Legally marketed device to which we are claiming “Substantial Equivalence” are the following:
Park's Pectus System - TDM Co. Ltd (K191057) (Predicate Device) (Primary)
Pectus Support Bar System - Biomet (K213712) (Predicate Device)
Versalock Rib and Sternum Plates System - GMReis (K232829) (Reference Device)
KLS Martin Pure Pectus System - KLS (K221938) (Reference Device)
Mini and Micro Fragments Reconstruction System - GMReis (K182718) (Reference Device)

IV. Device Description:

The Pectus Versa System consists of implants for treating chest wall deformities in adult and pediatric patients (children and adolescents). When implanted, the bars exert an internal force on the chest wall, enabling the repositioning of the bone structure of the thorax. The system has connecting bars and stabilizers that assist in the assembly of complex systems, stabilizing the system and connecting two or more bars, enabling the surgeon to apply minimally invasive techniques for treating chest wall deformities.

Pectus Versa System implants are manufactured with the following raw materials:

- Titanium Alloy Ti6Al4V according to ASTM F136 *"Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications"*

V. Statement of Indications for Use of the Device:

The Pectus Versa System is indicated for the treatment of Pectus Excavatum and other anterior chest wall deformities in adult and pediatric patients (children and adolescents).

VI. Comparison of Technological Characteristics with The Predicate Device:

The subject and predicate device have equivalent intended use and equivalent technological characteristics. Both devices are manufactured from identical materials and share equivalent design characteristics as well as physical dimensions. Any difference in technological characteristics do not raise new issues of safety or efficacy. The performance of the subject device was demonstrated through mechanical testing according to standards and predicate comparison. No clinical data were included in this submission.

VII. Performance Data:

Mechanical testing was performed according to ASTM F382-17 and all tests confirmed that the product met the predetermined acceptance criteria.

- Static and fatigue tensile construct testing to evaluate maximum load, displacement and runout load at 1 million cycles. The construct was oriented vertically, and connector bars were secured and loaded in tension. Performance was compared to the predicate in the same test set-up.
- Static and fatigue construct lateral bend testing to evaluate maximum load, displacement and runout load at 1 million cycles. The construct was oriented horizontally, one end of the construct was constrained, and the other end was bent downward in cantilever bend action. Performance was compared to the predicate in the same test set-up.

VIII. Conclusions:

As was established in this submission, the subject Pectus Versa System are equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to have the same technological characteristics, intended use, indications for use, material composition, anatomical region, multiple sizes, and basic design features compared to its predicate devices. Any differences between the subject and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. The information provided in this submission demonstrates that the proposed device is substantially equivalent to the predicate device.

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