June 26, 2024

GM Dos Reis Industria e Comercio Ltda
Guilherme Esteves Pontes
Regulatory Affairs Analyst
Avenida Pierre Simon de La Place 600
Campinas, SP 13069-320
Brazil

Re: K232829
Trade/Device Name: Versalock Rib and Sternum Plates 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, HWC
Dated: April 17, 2024
Received: April 17, 2024

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.

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,

Shumaya Ali -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232829

Device Name

Versalock Rib and Sternum Plates System

Indications for Use *(Describe)*

The Versalock Rib and Sternum Plates System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy, sternal reconstructive surgical procedures, rib and sternum fractures, fusions and osteotomies.

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.

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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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Guilherme Esteves Pontes, Regulatory Affairs Analyst
Telephone: +55 (19) 3765-9900, email: guilherme.qualidade@gmreis.com.br
Date prepared: June 26, 2024.

II. Device Name:

Trade Name:	Versalock Rib and Sternum Plates System
Common Name:	Plate, Fixation, Bone / Screw, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories / Smooth or threaded metallic bone fixation fastener
Device Class:	II
Product Codes:	HRS, HWC
Regulation Number:	21 CFR 888.3030, 888.3040

III. Predicate Devices:

Legally marketed devices to which we are claiming “Substantial Equivalence” are the following:
MatrixRIB Fixation System (K161590) (Primary predicate device).
Biomet Microfixation Sternal Closure System (K161896) (Additional predicate device).
Mini and Micro Fragments Reconstruction System (K182718) (Reference device).

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Suture Anchors - HTA Headless Titanium Anchor and Zip Anchors (K223114) (Reference device)
KLS Martin Thoracic Plating System (K153482) (Reference device).

IV. Device Description:

The Versalock Rib and Sternum Plates System is indicated for the stabilization and rigid fixation of chest wall fractures, including sternal reconstruction processes, trauma and/or planned osteotomies. The physical principle is based on rigid fixation, where the screws have a specific thread profile in their head, which, when fixed, allows the surgeon to fix it with a variable angle of ±15º in the threaded hole of the plate. The system also allows fixation with non-threaded head screws when the surgeon so desires. The devices are presented in Titanium Alloy according to the standard ASTM F136 and Pure Titanium According to ASTM F67.

V. Statement of Indications for Use of the Device:

The Versalock Rib and Sternum Plates System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy, sternal reconstructive surgical procedures, rib and sternum fractures, fusions and osteotomies.

VI. Comparison of Technological Characteristics with The Predicate Device:

The subject device is substantially equivalent in indications and design principles to the following predicate devices:
K161590 - MatrixRIB Fixation System - DePuy Synthes
K161896 - Biomet Microfixation Sternal Closure System - Biomet Microfixation
The subject and predicate devices have equivalent intended use and equivalent technological characteristics. The subject and predicate devices are all manufactured from identical materials and share equivalent design characteristics. The subject and predicate devices encompass equivalent physical dimensions. Any difference in the technological

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characteristics do not raise new issues of safety or efficacy. The performance of the subject devices was compared with the predicates and are demonstrated through mechanical testing according to ASTM F543 and ASTM F382. No clinical data were included in this submission. The subject devices could be provided in sterile condition sterilized by Ethylene Oxide or non-sterile condition to end user, the non-sterile version must be cleaned, and steam sterilized before use. Pyrogen test according to USP <151> was conducted to demonstrate that the device meets pyrogen limit specifications.

VII. Performance Data:

The non-clinical tests performed and the Recognized Consensus Standards to which the Versalock Rib and Sternum Plates System have been tested are specifically the following:

- Torsional Properties of Metallic Bone Screws per ASTM F543
- Driving Torque of Medical Bone Screws per ASTM F543
- Axial Pullout Strength of Medical Bone Screws per ASTM F543
- Single Cycle Bending Test (Static) per ASTM F382
- Bending Fatigue Test per ASTM F382
- Lateral Distraction, Longitudinal and Transversal Shear

VIII. Conclusions:

As was established in this submission, the subject Versalock Rib and Sternum Plates System are substantially equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and 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 Versalock Rib and Sternum Plates System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.

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