December 8, 2023

JM Longyear Manufacturing, LLC d/b/a Able Medical Devices
Katie Barron
Project Manager
512 4th Street
Gwinn, Michigan 49841

Re: K232515
Trade/Device Name: Valkyrie Thoracic Fixation 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: August 18, 2023
Received: August 18, 2023

Dear Katie Barron:

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, MPH
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K232515

Device Name
Valkyrie Thoracic Fixation System

Indications for Use *(Describe)*
The Valkyrie Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system is intended for use in patients with normal and/or poor bone quality.

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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# K232515
# 510(k) Summary

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| Date Prepared: | August 18, 2023 |
| 510(k) Owner / Manufacturer: | JM Longyear Manufacturing, LLC d/b/a Able Medical Devices<br>512 4th Street<br>Gwinn, MI 49841 |
| Contact Person: | Katie Barron<br>Able Medical Devices<br>Phone: (906) 372-3213<br>Email: KatieB@abledev.us |
| Trade or Proprietary Name: | Valkyrie Thoracic Fixation System |
| Common or Usual Name: | Bone Plate |
| Classification: | Class II per 21 CFR §888.3030 (primary) and 21 CFR §888.3040 |
| Regulation Name: | Single/multiple component metallic bone fixation appliances and accessories (primary); Screw, Fixation, Bone |
| Product Code: | HRS (primary), HWC |
| Classification Panel: | Panel Code 87: Orthopedics |
| Primary Predicate | K202889 Valkyrie Thoracic Fixation System |
| Additional Predicate | K221412 JEIL Medical ARIX Rib System |
| Description | The Valkyrie Thoracic Fixation System consists of a variety of screws and plates intended for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system is intended for use in patients with normal and/or poor bone quality.<br><br>To accommodate varying patient anatomy and surgeon preference, the Valkyrie Thoracic Fixation System includes screws in diameters from 2.5mm to 3.5mm diameters and lengths from 7-20mm. The system also includes various styles of plates. The Valkyrie Thoracic Fixation System plates are made from PEEK per ASTM F2026, and the screws are made from Ti-6Al-4V per ASTM F136. |
| Indications for Use | The Valkyrie Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system is intended for use in patients with normal and/or poor bone quality. |

Summary of Technological Characteristics

The subject Valkyrie Thoracic Fixation System has nearly identical technological characteristics as the primary predicate device cleared for use in stabilization and fixation of fractures in the chest wall. Similarities to the predicate device include:

- Identical indications for use while clarifying the term "indicated for"
- Identical principles of operation and fundamental technology: intended to stabilize and fixate fractures of the anterior chest wall through the use of plates and screws
- Identical implant materials and manufacturing processes
- Identical sterilization processes

| | | **Able Medical Devices Valkyrie Thoracic Fixation System (Subject Device)** | **PRIMARY PREDICATE: Able Medical Devices Valkyrie Thoracic Fixation System (K202889, K211695)** |
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| **Indications for Use:** | | The Valkyrie Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system is intended for use in patients with normal and/or poor bone quality. | The Valkyrie Thoracic Fixation System is intended for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system is intended for use in patients with normal and/or poor bone quality. |
| **Sterility:** | | Provided Sterile | Provided Sterile |
| **Plate Features:** | **Configurations:** | Rib Plate | Rib Plate, V-Plate, Box Plate, X-Plate, M-Plate, T-Plate, Ladder Plate |
| | **# Screw Holes:** | 8 to 16 | 4 to 16 |
| | **Material:** | PEEK per ASTM F2026 | PEEK per ASTM F2026 |
| **Screw Features:** | **Diameter:** | Ø2.5mm, Ø2.8mm | Ø3.0mm, Ø3.5mm |
| | **Length:** | 7mm – 15mm | 7mm – 20mm |
| | **Material:** | Ti-6Al-4V per ASTM F136 | Ti-6Al-4V per ASTM F136 |

The differences of the subject devices as compared to the primary predicate device are as follows:

- Updated labeling to include MR conditional
- Inclusion of additional plate and screw sizes
  - Additional predicate K212412 is included to leverage the technological characteristics of the smaller screw sizes

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| Discussion of Supporting Non-Clinical Testing | To support the inclusion of MR Conditional labeling, the following tests were completed:<br>• Magnetically induced displacement force per ASTM F2052<br>• Magnetically induced torque per ASTM F2213<br>• MR Image artifact per ASTM F2119<br>• Radio frequency induced heating per ASTM F2182<br><br>To support the inclusion of additional screw sizes, the following tests were completed:<br>• Screw torsional strength testing per ASTM F543<br>• Screw axial pullout strength testing per ASTM F543<br>• Screw driving torque testing per ASTM F543<br><br>All testing has met the documented acceptance criteria. |
| Clinical Performance Data | Clinical testing was not necessary for the determination of substantial equivalence. |
| Substantial Equivalence | The subject device is substantially equivalent to the Valkyrie Thoracic Fixation System (K202889) in terms of material composition, manufacturing process, sterilization, and packaging and both are manufactured in the same facility.<br><br>The subject device and the predicate device have the same intended uses, the same product classification and produce code and have identical Indications for Use statements. The subject device and the predicate incorporate the same basic design, same materials, have identical manufacturing processes, and are both provided sterile for single-patient and single-use. |
| Conclusion | The overall technological similarities to the predicate and non-clinical performance data lead to the conclusion that the Valkyrie Thoracic Fixation System is substantially equivalent to the predicate system. The devices are determined to be MR Conditional based on the results of testing completed. |