June 23, 2021

JM Longyear Manufacturing, LLC d/b/a Able Medical Devices
Wade Depas
Director, Quality & Product Development
512 4th Street
Gwinn, Michigan 49841

Re: K211695
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: June 2, 2021
Received: June 2, 2021

Dear Wade Depas:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211695

Device Name
Valkyrie Thoracic Fixation System

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Date Prepared:	June 2nd, 2021
510(k) Owner / Manufacturer:	JM Longyear Manufacturing, LLC d/b/a Able Medical Devices 512 4th Street, Gwinn, MI 49841 http:///www.ablemedicaldevices.com Establishment Registration #3014680795
Contact Person:	Wade DePas | Director, Quality & Product Development Able Medical Devices Phone: (906) 360-4670 Email: WadeD@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
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. To accommodate varying patient anatomy and surgeon preference, the Valkyrie Thoracic Fixation System includes screws in 3.0mm and 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-Optima™ per ASTM F2026, and the screws are made from Ti-6Al-4V per ASTM F136.
Purpose of Submission	Obtain clearance for the following modification to the predicate K202889 Valkyrie Thoracic Fixation System: addition of Caddy Guide Instrument (Device specific Instrument).
Indications for Use	This 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.

Summary of Technological Characteristics	The subject Valkyrie Thoracic Fixation System has similar technological characteristics as the predicate K202889 devices cleared for use in closure of the sternum. Similarities to the predicate device include: • Identical indications for use • Identical principles of operation and fundamental technology: intended to stabilize and fixate fractures of the anterior chest wall (e.g., sternal fixation) through the use of plates and screws. • Identical sterilization/cleaning • Identical packaging/expiration dating • Identical implant components The addition of the Caddy Guide instrument is supported by nonclinical testing listed below.
Discussion of Supporting Non-Clinical Testing	The following nonclinical tests were submitted and relied upon in this premarket notification submission for a determination of substantial equivalence. Testing identified in Design Control Activities Summary has all met acceptance criteria established by the associated recognized standards: • Biocompatibility o Cytotoxicity (ISO 10993-5:2009) o Sensitization (ISO 10993-10:2010) o Irritation or Intracutaneous Reactivity (ISO 10993-10:2010) o Acute Systemic toxicity (ISO 10993-11:2017) o Material-Mediated Pyrogenicity (ISO 10993-11:2017)
Conclusion	The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met. The Valkyrie Thoracic Fixation System is shown to be substantially equivalent to the predicate system. The subject device is as safe, as effective, as the predicate device.