March 2, 2021

JM Longyear Manufacturing, LLC D.B.A. Able Medical Devices
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K202889
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
Dated: January 25, 2021
Received: January 26, 2021

Dear Nathan Wright:

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,

For; 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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K202889

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.

510(K) SUMMARY - K202889

Submitter's Name:	Able Medical Devices
Submitter's Address:	512 4th Street Gwinn, MI 49841
Submitter's Telephone:	906-372-3213
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	September 25, 2020
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:	Orthopedics

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

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.

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.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K163007, K151019, K121302, K110574	Biomet Microfixation Sternalock 360 Sternal Closure System	Biomet Microfixation	Primary
K193468, K133785	Tritium Sternal Cable Plate System	Pioneer Surgical Technology, Inc.	Additional
K151983	KLS Martin LSS Plating System	KLS Martin L.P.	Additional
K170767	Stainless Steel Suture	Ethicon Incorporated	Additional

PERFORMANCE DATA

The Valkyrie Thoracic Fixation System has been tested in the following test modes:

- Static construct tension
- Dynamic construct tension
- Biocompatibility
    - Cytotoxicity (ISO 10993-5:2009)
    - Systemic toxicity (ISO 10993-11:2017)
    - Genotoxicity (ISO 10993-3:2014)
    - Intracutaneous irritation (ISO 10993-10:2010)
    - Pyrogenicity (ISO 10993-11:2017)
    - Sensitization (ISO 10993-10:2010)
    - Chemical characterization (ISO 10993-18:2020)
- Sterilization validation (ISO 11137-1:2006)
- Packaging Shelf-life (ASTM 1980)
- Packing Peel Strength (ASTM F88)
- Packaging integrity validation (ASTM F1886, ASTM F1929, ASTM F2096)

The results of this non-clinical testing show that the strength of the Valkyrie Thoracic Fixation System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Valkyrie Thoracic Fixation System is substantially equivalent to the predicate device.