

K202889 Able Medical Devices Valkyrie Thoracic Fixation SystemMar 2, 2021
155 days to decisionK202889 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k202889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 28, 2020
Decision date	Mar 2, 2021
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jm Longyear Manufacturing, LLC D.B.A. Able Medical Devices
Location	Gwinn, MI, US
Contact	Wade DePas
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Nathan Wright

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202889/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026