

K211695 Valkyrie Thoracic Fixation SystemJun 23, 2021
21 days to decisionK211695 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k211695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 2, 2021
Decision date	Jun 23, 2021
Days to decision	21 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211695/> 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 26, 2026