

K232515 Valkyrie Thoracic Fixation SystemDec 8, 2023
112 days to decisionK232515 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k232515/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Aug 18, 2023 |
| Decision date | Dec 8, 2023 |
| Days to decision | 112 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 | Katie Barron |
| 510(k) history | 3 submissions · 3 cleared · 2021-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232515/> 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