

K250933 LORRAINE 2.5/3.5mm Distal Humerus SystemJun 11, 2025
75 days to decisionK250933 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k250933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 28, 2025
Decision date	Jun 11, 2025
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bonebridge AG
Location	Zug, CH
Contact	Michelle Gumpelmayer
510(k) history	9 submissions · 9 cleared · 2021-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250933/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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