

K260228 POYA 3.5mm Medial Proximal Tibia SystemApr 24, 2026
88 days to decisionK260228 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k260228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 26, 2026
Decision date	Apr 24, 2026
Days to decision	88 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

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