

K252061 Distal Xtremities SystemAug 20, 2025
50 days to decisionK252061 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k252061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 1, 2025
Decision date	Aug 20, 2025
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	TriMed, Inc.
Location	Saugus, CA, US
Contact	Blesson Abraham
510(k) history	35 submissions · 35 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	Tech2med, LLC
Contact	Kelli Anderson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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