FDA 510(k) Premarket Notification

K252061 Distal Xtremities System

CLEARED

Aug 20, 2025
50 days to decision

K252061 · 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