

**K243999 TriMed Ankle Fixation System**Mar 19, 2025  
83 days to decisionK243999 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k243999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 26, 2024
Decision date	Mar 19, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>TriMed, Inc.</b>
Location	Saugus, CA, US
Contact	Divya Raghavi Nandakumar
510(k) history	35 submissions · 35 cleared · 2005-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243999/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026