

**K243987 TriMed Elbow and Forearm System**Mar 19, 2025  
86 days to decisionK243987 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k243987/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 23, 2024
Decision date	Mar 19, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243987/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026