

K254087 MAXFRAME AUTOSTRUT™ with Bluetooth Multi-Axial Correction SystemJun 11, 2026
175 days to decisionK254087 · Product code: KTT · Orthopedic
Source: <https://www.510kdatabase.net/k254087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Dec 18, 2025
Decision date	Jun 11, 2026
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes USA Products, LLC
Location	West Chester, PA, US
Contact	Mitchel Bartko
510(k) history	61 submissions · 61 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254087/>; 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 July 11, 2026