

K260112 QuikFix External Fixator: Knee-Spanning PackMar 23, 2026
68 days to decisionK260112 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k260112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jan 14, 2026
Decision date	Mar 23, 2026
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stabiliz Orthopaedics, Inc.
Location	Exton, PA, US
Contact	Douglas Cerynik
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	Hannah Irwin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260112/> 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 13, 2026