

**K250628 DynaNail TTC Fusion System**Sep 12, 2025  
193 days to decisionK250628 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k250628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Mar 3, 2025
Decision date	Sep 12, 2025
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MedShape, Inc.</b>
Location	Atlanta, GA, US
Contact	Amberlee Soto
510(k) history	16 submissions · 16 cleared · 2012-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250628/> 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