

**K202858 Flex-Thread™ Distal Fibula Intramedullary Nail System**Jan 22, 2021  
116 days to decisionK202858 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k202858/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Sep 28, 2020
Decision date	Jan 22, 2021
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Conventus Orthopaedics, LLC</b>
Location	Maple Grove, MN, US
Contact	Amanda Pentecost
510(k) history	1 submissions · 1 cleared · 2021-2021

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202858/> 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 27, 2026