

**K083458 INTRAMEDULLARY FIXATION ROD (IFS)**Feb 9, 2009  
80 days to decisionK083458 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k083458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Nov 21, 2008
Decision date	Feb 9, 2009
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Noalign Orthopaedics, Inc.</b>
Location	Memphis, TN, US
Contact	JEFFREY G ROBERTS
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083458/> 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 19, 2026