

**K181375 Apex Femoral Nailing System**Jul 17, 2018  
54 days to decisionK181375 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k181375/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 24, 2018
Decision date	Jul 17, 2018
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthoxel</b>
Location	Bishopstown, IE
Contact	Aisling O'Sullivan
510(k) history	2 submissions · 2 cleared · 2017-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181375/> 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 16, 2026