

**K132733 ORTHOHELIX SYNDESMOSIS FIXATION DEVICES**Jan 3, 2014  
122 days to decisionK132733 · Product code: **HTN** · Orthopedic  
Source: <https://www.510kdatabase.net/k132733/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Sep 3, 2013
Decision date	Jan 3, 2014
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthohelix Surgical Designs, Inc.</b>
Location	Cleveland, OH, US
Contact	BRIAN HOCKETT
510(k) history	25 submissions · 25 cleared · 2005-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132733/> 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 17, 2026