

**K161058 Cannulated Screw**Jul 29, 2016  
105 days to decisionK161058 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k161058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 15, 2016
Decision date	Jul 29, 2016
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Miami Device Solutions, LLC</b>
Location	Miami, FL, US
Contact	MARKKU BIEDERMANN
510(k) history	6 submissions · 6 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161058/> 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 June 28, 2026