

**K080358 PLLA, HA SCREW**Apr 23, 2008  
72 days to decisionK080358 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k080358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 11, 2008
Decision date	Apr 23, 2008
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smith &amp; Nephew Inc., Endoscopy Div.</b>
Location	Andover, MA, US
Contact	DEANA BOUSHELL
510(k) history	10 submissions · 10 cleared · 2007-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080358/> 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 26, 2026