

**K140576 Y WIRE 2**May 20, 2014  
75 days to decisionK140576 · Product code: **HXI** · Orthopedic  
Source: <https://www.510kdatabase.net/k140576/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Passer, Wire, Orthopedic (HXI)
Date received	Mar 6, 2014
Decision date	May 20, 2014
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Safewire, LLC</b>
Location	Holland, MI, US
Contact	STEPHEN W INGLESE
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140576/> 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