

**K151418 Monster Screw System**Jul 15, 2015  
48 days to decisionK151418 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k151418/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 28, 2015
Decision date	Jul 15, 2015
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Paragon 28</b>
Location	Chesterland, OH, US
Contact	FRANK S. BONO
510(k) history	7 submissions · 7 cleared · 2014-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151418/> 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