

**K172886 Breakaway Screw System**Dec 20, 2017  
90 days to decisionK172886 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k172886/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 21, 2017
Decision date	Dec 20, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Paragon 28</b>
Location	Chesterland, OH, US
Contact	Eric Lintula
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/k172886/> 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