

**K080667 VARIAX DISTAL RADIUS TORX SCREWS**Mar 19, 2008  
9 days to decisionK080667 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k080667/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 10, 2008
Decision date	Mar 19, 2008
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Howmedica Osteonics Corp.</b>
Location	Allendale, NJ, US
Contact	DANIELLE HILLMAN
510(k) history	288 submissions · 288 cleared · 1999-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080667/> 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 15, 2026