

**K970912 LEIBINGER SELF-DRILLING SCREW**Oct 1, 1997  
203 days to decisionK970912 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k970912/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Mar 12, 1997
Decision date	Oct 1, 1997
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Howmedica Leibinger, Inc.</b>
Location	Dallas, TX, US
Contact	KRISTYN WASKI
510(k) history	11 submissions · 10 cleared · 1996-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970912/> 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 21, 2026