

**K970549 TITANIUM ALLOY BONE SCREWS**Apr 30, 1997  
77 days to decisionK970549 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k970549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 12, 1997
Decision date	Apr 30, 1997
Days to decision	77 days
Third-party review	No

**APPLICANT**

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Company	<b>Aesculap, Inc.</b>
Location	Burlingame, CA, US
Contact	VICTORIA MACKINNON
510(k) history	207 submissions · 201 cleared · 1991-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970549/>; 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