

**K963077 TBD**Oct 1, 1996  
54 days to decisionK963077 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k963077/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Aug 8, 1996
Decision date	Oct 1, 1996
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acu Med, Inc.</b>
Location	Beaverton, OR, US
Contact	SHARI L JEFFERS
510(k) history	48 submissions · 39 cleared · 1990-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963077/> 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 14, 2026