

**K943857 EXTERNAL FIXATOR**Jan 27, 1995  
172 days to decisionK943857 · Product code: **JEC** · Orthopedic  
Source: <https://www.510kdatabase.net/k943857/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Component, Traction, Invasive (JEC)
Date received	Aug 8, 1994
Decision date	Jan 27, 1995
Days to decision	172 days
Third-party review	No

**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/k943857/>; 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