

**K973644 FLOSTAT VASCULAR LAB**Dec 23, 1997  
90 days to decisionK973644 · Product code: **JAF** · Radiology  
Source: <https://www.510kdatabase.net/k973644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Nonfetal (JAF)
Date received	Sep 24, 1997
Decision date	Dec 23, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biomedix, Inc.</b>
Location	Spencer, IN, US
Contact	DAVID LERNER
510(k) history	11 submissions · 11 cleared · 1993-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973644/> 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 20, 2026