

**K010521 NICOLET VERSALAB**Mar 9, 2001  
15 days to decisionK010521 · Product code: **JAF** · Radiology  
Source: <https://www.510kdatabase.net/k010521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Ultrasonic, Nonfetal (JAF)
Date received	Feb 22, 2001
Decision date	Mar 9, 2001
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nicolet Biomedical</b>
Location	Golden, CO, US
Contact	DAVID W WAGNER
510(k) history	8 submissions · 8 cleared · 1998-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010521/> 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 19, 2026