

**K982639 SPIFE URINE IFE**Nov 4, 1998  
98 days to decisionK982639 · Product code: **DAO** · Immunology  
Source: <https://www.510kdatabase.net/k982639/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igm (mu Chain Specific), Antigen, Antiserum, Control (DAO)
Date received	Jul 29, 1998
Decision date	Nov 4, 1998
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982639/> 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