

**K991067 MODIFICATION OF: DAVIDSTRIP HCG**Apr 27, 1999  
28 days to decisionK991067 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k991067/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 30, 1999
Decision date	Apr 27, 1999
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Simex Medical, Inc.</b>
Location	Tukwila, WA, US
Contact	MICHELLE J HALL
510(k) history	1 submissions · 1 cleared · 1999-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991067/> 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 June 30, 2026