

**K960992 BIONIKE A/Q PREGNANCY TEST**Apr 25, 1996  
44 days to decisionK960992 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k960992/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 12, 1996
Decision date	Apr 25, 1996
Days to decision	44 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bionike Laboratories, Inc.</b>
Location	Sunnyvale, CA, US
Contact	JANIS FREESTONE
510(k) history	6 submissions · 6 cleared · 1995-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k960992/> 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 28, 2026