

**K964633 ACCUPACK PREGNANCY TEST**Feb 20, 1997  
93 days to decisionK964633 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k964633/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Nov 19, 1996
Decision date	Feb 20, 1997
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Genix Biotek, Inc.</b>
Location	San Diego, CA, US
Contact	RICHARD WANG
510(k) history	2 submissions · 2 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964633/> 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 July 1, 2026