

**K925303 PRO-STEP PT HCG**Jun 15, 1993  
237 days to decisionK925303 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k925303/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 21, 1992
Decision date	Jun 15, 1993
Days to decision	237 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Disease Detection International, Inc.</b>
Location	Irvine, CA, US
Contact	SIEGFRIED KRUTZIK
510(k) history	20 submissions · 20 cleared · 1988-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k925303/> 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