

**K915197 PRECISE TM HCG**Dec 17, 1991  
28 days to decisionK915197 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k915197/>**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, 1991
Decision date	Dec 17, 1991
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Becton Dickinson Advanced Diagnostics</b>
Location	Cockeysville, MD, US
Contact	JUDITH J SMITH
510(k) history	10 submissions · 10 cleared · 1991-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915197/> 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