

**K911050 LH IRMA IMMUNOMAG**Apr 12, 1991  
35 days to decisionK911050 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k911050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Mar 8, 1991
Decision date	Apr 12, 1991
Days to decision	35 days
Third-party review	No

**APPLICANT**

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Company	<b>Pantex, Div. Bio-Analysis, Inc.</b>
Location	Mchenry, IL, US
Contact	NEIL Y CHIAMORI
510(k) history	16 submissions · 16 cleared · 1981-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911050/>, 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 14, 2026