

**K850530 LEECO CONCEP-7-BHCG IRMA**Apr 2, 1985  
50 days to decisionK850530 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k850530/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 11, 1985
Decision date	Apr 2, 1985
Days to decision	50 days
Third-party review	No

**APPLICANT**

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Company	<b>Leeco Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	JAMES P LEE
510(k) history	49 submissions · 49 cleared · 1979-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850530/>, 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