

**K891770 HCG IRMA II**May 24, 1989  
61 days to decisionK891770 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k891770/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 24, 1989
Decision date	May 24, 1989
Days to decision	61 days
Third-party review	No

**APPLICANT**

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Company	<b>Pacific Biotech, Inc.</b>
Location	Mchenry, IL, US
Contact	SHU-CHING CHENG
510(k) history	29 submissions · 29 cleared · 1983-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891770/>, 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