

**K811116 HCG RADIOIMMUNOASSAY**May 13, 1981  
19 days to decisionK811116 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k811116/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 24, 1981
Decision date	May 13, 1981
Days to decision	19 days
Third-party review	No

**APPLICANT**

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Company	<b>Hoffmann-La Roche, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.roche.com">https://www.roche.com</a>
510(k) history	49 submissions · 49 cleared · 1976-1985

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k811116/>; 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 29, 2026