

**K820614 ROCHE B-HCG STANDARDS**Apr 1, 1982  
24 days to decisionK820614 · Product code: **JHI** · ChemistrySource: <https://www.510kdatabase.net/k820614/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 8, 1982
Decision date	Apr 1, 1982
Days to decision	24 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/k820614/>; 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