

K791206 HCG RIA PREGNANCY TESTJul 30, 1979
31 days to decisionK791206 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k791206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jun 29, 1979
Decision date	Jul 30, 1979
Days to decision	31 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k791206/>; Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026