

K801244 ROCHE HCG STANDARDSJun 20, 1980
24 days to decisionK801244 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k801244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	May 27, 1980
Decision date	Jun 20, 1980
Days to decision	24 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

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