FDA 510(k) Premarket Notification

K820614 ROCHE B-HCG STANDARDS

CLEARED

Apr 1, 1982
24 days to decision

K820614 · Product code: **JHI** · Chemistry
Source: https://www.510kdatabase.net/k820614/

SUBMISSION DETAILS

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

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