

K850727 BHCg-ROCHE EIAJun 25, 1985
123 days to decisionK850727 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k850727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 22, 1985
Decision date	Jun 25, 1985
Days to decision	123 days
Third-party review	No

APPLICANT

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

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