

K822219 HUMAN PLASMA CONTROL FOR CEA-ROCHEDec 28, 1982
155 days to decisionK822219 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k822219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jul 26, 1982
Decision date	Dec 28, 1982
Days to decision	155 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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