

K003967 CA 125 II CALCHECKJan 12, 2001
21 days to decisionK003967 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k003967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 22, 2000
Decision date	Jan 12, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	KAY A TAYLOR
510(k) history	264 submissions · 263 cleared · 1999-2013

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