

K101365 ELECSYS CA 19-9 CALCHECK 5Oct 5, 2010
141 days to decisionK101365 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k101365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	May 17, 2010
Decision date	Oct 5, 2010
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	KELLY O'NEILL MAINE ADAMS
510(k) history	264 submissions · 263 cleared · 1999-2013

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