

K051185 ELECSYS CA 19-9 CALCHECKJul 6, 2005
58 days to decisionK051185 · Product code: **JJY** · Immunology
Source: <https://www.510kdatabase.net/k051185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	May 9, 2005
Decision date	Jul 6, 2005
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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