

K092888 ELECSYS TOXO IGG CALCHECK 5Nov 10, 2009
50 days to decisionK092888 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k092888/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 21, 2009
Decision date	Nov 10, 2009
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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