

K093700 ELECSYS HCG STAT CALCHECK 5Mar 4, 2010
93 days to decisionK093700 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k093700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 1, 2009
Decision date	Mar 4, 2010
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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