

K092848 ELECSYS TROPONIN T CALCHECK 5Mar 19, 2010
184 days to decisionK092848 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k092848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 16, 2009
Decision date	Mar 19, 2010
Days to decision	184 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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