

K031990 ELECSYS PRECICONTROL TROPONIN TAug 20, 2003
54 days to decisionK031990 · Product code: **JJX** · Toxicology
Source: <https://www.510kdatabase.net/k031990/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 27, 2003
Decision date	Aug 20, 2003
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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