

K033873 ELECSYS C-PEPTIDE CALSETFeb 13, 2004
60 days to decisionK033873 · Product code: **JIX** · Toxicology
Source: <https://www.510kdatabase.net/k033873/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Dec 15, 2003
Decision date	Feb 13, 2004
Days to decision	60 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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