

K031299 ELECSYS LH CALSET IIMay 12, 2003
18 days to decisionK031299 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k031299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Apr 24, 2003
Decision date	May 12, 2003
Days to decision	18 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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