

K003409 ELECSYS FSH CALSET IIJan 26, 2001
85 days to decisionK003409 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k003409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 2, 2000
Decision date	Jan 26, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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