

K012399 MODIFICATION TO ELECSYS FSH II CALSETAug 24, 2001
28 days to decisionK012399 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k012399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Jul 27, 2001
Decision date	Aug 24, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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