

K042490 ELECSYS FOLATE II CALSET IISep 30, 2004
16 days to decisionK042490 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k042490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Sep 14, 2004
Decision date	Sep 30, 2004
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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