

**K043320 MODIFICATION TO ROCHE ELECSYS FOLATE II
CALCHECK II**Dec 17, 2004
15 days to decisionK043320 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k043320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 2, 2004
Decision date	Dec 17, 2004
Days to decision	15 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043320/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026