

**K043318 MODIFICATION TO ROCHE ELECSYS FOLATE II
IMMUNOASSAY**Dec 23, 2004
21 days to decisionK043318 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k043318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Dec 2, 2004
Decision date	Dec 23, 2004
Days to decision	21 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/k043318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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