

K031756 ROCHE DIAGNOSTICS ELECSYS FOLATE II ASSAYJun 25, 2003
19 days to decisionK031756 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k031756/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Jun 6, 2003
Decision date	Jun 25, 2003
Days to decision	19 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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