

K051292 ELECSYS RBC FOLATE HEMOLYZED REAGENTJun 17, 2005
30 days to decisionK051292 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k051292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	May 18, 2005
Decision date	Jun 17, 2005
Days to decision	30 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

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