

**K082340 ROCHE ELECSYS FOLATE III, ROCHE ELECSYS RBC FOLATE HEMOLYSING REAGENT, ROCHE ELECSYS FOLATE III CALSET, ROCHE ELECSYS**Jun 19, 2009  
308 days to decisionK082340 · Product code: **CGN** · Chemistry  
Source: <https://www.510kdatabase.net/k082340/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Aug 15, 2008
Decision date	Jun 19, 2009
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	KATHIE J GOODWIN
510(k) history	264 submissions · 263 cleared · 1999-2013

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