

K103716 ROCHE ELECSYS FOLATE RBCMay 12, 2011
142 days to decisionK103716 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k103716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Dec 21, 2010
Decision date	May 12, 2011
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary
Other names	ROCHE ELECSYS FOLATE RBC CALSET

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	KATHIE J GOODWIN
Website	https://diagnostics.roche.com
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...