

**K981931 CEDIA RED BLOOD CELL FOLATE REAGENT PACK,
CEDIA FOLATE ASSAY AND ELECSYS FOLATE ASSAY**Aug 25, 1998
84 days to decisionK981931 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k981931/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Jun 2, 1998
Decision date	Aug 25, 1998
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics/Boehringer Mannheim GmbH
Location	Indianapolis, IN, US
Contact	Patricia M Klimley
510(k) history	3 submissions · 3 cleared · 1998-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981931/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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