

K960800 CEDIA RED BLOOD CELL FOLATE (NO BOIL REAGENT PACK)Jul 26, 1996
150 days to decisionK960800 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k960800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Feb 27, 1996
Decision date	Jul 26, 1996
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	MARY KONING
510(k) history	340 submissions · 340 cleared · 1976-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k960800/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026