

**K010050 ADVIA CENTAUR AND ACS: 180 FOLATE
IMMUNOASSAY**Feb 5, 2001
31 days to decisionK010050 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k010050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Jan 5, 2001
Decision date	Feb 5, 2001
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Diagnostics Corp.
Location	Medfield, MA, US
Contact	THOMAS F FLYNN
510(k) history	32 submissions · 32 cleared · 2000-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010050/>; 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 June 28, 2026