

K012357 CA 15-3 ASSAY FOR THE ADVIA CENTAUR SYSTEMFeb 28, 2002
218 days to decisionK012357 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k012357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Jul 25, 2001
Decision date	Feb 28, 2002
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Diagnostics Corp.
Location	Medfield, MA, US
Contact	KENNETH T EDDES
510(k) history	32 submissions · 32 cleared · 2000-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012357/> 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