

K031857 ADVIA CHEMISTRY ALPHA-1 ANTITRYPSIN ASSAYSep 4, 2003
80 days to decisionK031857 · Product code: **DEM** · Chemistry
Source: <https://www.510kdatabase.net/k031857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin, Antigen, Antiserum, Control (DEM)
Date received	Jun 16, 2003
Decision date	Sep 4, 2003
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031857/> 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