

**K982551 ROCHE COBAS INTEGRA SERUM BARBITURATES
REAGENT CASSETTE, ABUSCREEN ONLINE SERUM
BARBITURATES CALIBRATORS, ROCHE COBAS IN**Aug 18, 1998
27 days to decisionK982551 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k982551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Jul 22, 1998
Decision date	Aug 18, 1998
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982551/>. 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 22, 2026