

**K983698 MODIFICATION TO ABUSCREEN ONLINE
BARBITURATES**May 3, 1999
194 days to decisionK983698 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k983698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Oct 21, 1998
Decision date	May 3, 1999
Days to decision	194 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/k983698/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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