FDA 510(k) Premarket Notification

K931125 ABUSCREEN ONLINE CONTROL

CLEARED

Aug 3, 1993
152 days to decision

K931125 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k931125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Mar 4, 1993
Decision date	Aug 3, 1993
Days to decision	152 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k931125/ 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 23, 2026