

**K935550 ABUSCREEN ONLINE NEGATIVE CAL/CONTROL CAL
PACK AND MIL CALIBRATION PACK**Jan 3, 1994
47 days to decisionK935550 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k935550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Nov 17, 1993
Decision date	Jan 3, 1994
Days to decision	47 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.netDevice record: <https://www.510kdatabase.net/k935550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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