FDA 510(k) Premarket Notification

K932754 ABUSCREEN CALIBRATION STANDARD

CLEARED

Jul 22, 1993
55 days to decision

K932754 · Product code: **DKB** · Toxicology
Source: https://www.510kdatabase.net/k932754/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	May 28, 1993
Decision date	Jul 22, 1993
Days to decision	55 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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