

K945194 ABUSCREEN ONLINE CONTROLSDec 9, 1994
46 days to decisionK945194 · Product code: **DIF** · Toxicology
Source: <https://www.510kdatabase.net/k945194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Oct 24, 1994
Decision date	Dec 9, 1994
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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