

K943999 ABUSCREEN ONTRAK POSITIVE CONTROLJan 25, 1995
187 days to decisionK943999 · Product code: **DIF** · Toxicology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jul 22, 1994
Decision date	Jan 25, 1995
Days to decision	187 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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