

K914806 ABUSCREEN(R) ONTRAK(R) POSITIVE REFERENCE CONTROLNov 19, 1991
26 days to decisionK914806 · Product code: **DIF** · Toxicology
Source: <https://www.510kdatabase.net/k914806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Oct 24, 1991
Decision date	Nov 19, 1991
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	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

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