

K983388 ONTRAK TESTCUP-ERNov 18, 1998
54 days to decisionK983388 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k983388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Sep 25, 1998
Decision date	Nov 18, 1998
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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