

K983697 MODIFICATION TO ABUSCREEN ONLINE COCAINE METABOLITEDec 11, 1998
51 days to decisionK983697 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k983697/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Oct 21, 1998
Decision date	Dec 11, 1998
Days to decision	51 days
Third-party review	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

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