

K890885 ABUSCREEN FP FOR COCAINE METABOLITEMar 13, 1989
20 days to decisionK890885 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k890885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Feb 21, 1989
Decision date	Mar 13, 1989
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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