

K863843 COCAINE METABOLITE ROCHE(R) EIAMar 16, 1987
166 days to decisionK863843 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k863843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Oct 1, 1986
Decision date	Mar 16, 1987
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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