

**K874271 REVISED LABELING FOR COCAINE/COCAINE META.
TEST**Nov 13, 1987
24 days to decisionK874271 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k874271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Oct 20, 1987
Decision date	Nov 13, 1987
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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