

K881815 ABUSCREEN(R) ONTRAK(TM) FOR COCAINEJul 29, 1988
92 days to decisionK881815 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k881815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 28, 1988
Decision date	Jul 29, 1988
Days to decision	92 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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