

**K944231 ONTRAK TESTCUP COLLECTION/URINALYSIS PANEL
FOR COCAINE, MORPHINE AND THC**Dec 2, 1994
93 days to decisionK944231 · Product code: **DIO** · Chemistry
Source: <https://www.510kdatabase.net/k944231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Aug 31, 1994
Decision date	Dec 2, 1994
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944231/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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