

**K994165 ONTRAK TESTSTIK 3 FOR
COCAINE/MORPHINE/THC,CAT. 1118595**Apr 7, 2000
120 days to decisionK994165 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k994165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Dec 9, 1999
Decision date	Apr 7, 2000
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	JENNIFER TRIBBETT
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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