

K990418 ONTRAK TESTCUP-ER M2KApr 13, 1999
62 days to decisionK990418 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k990418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Feb 10, 1999
Decision date	Apr 13, 1999
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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