

K001421 ONTRAK TESTCUP 501, MODEL 3016633Jul 12, 2000
68 days to decisionK001421 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k001421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	May 5, 2000
Decision date	Jul 12, 2000
Days to decision	68 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

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