

K012396 ONTRAK TESTCARD 9Nov 5, 2001
101 days to decisionK012396 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k012396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jul 27, 2001
Decision date	Nov 5, 2001
Days to decision	101 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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