

K093664 AMPHETAMINES II ASSAYJul 28, 2010
243 days to decisionK093664 · Product code: **DKZ** · Chemistry
Source: <https://www.510kdatabase.net/k093664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Nov 27, 2009
Decision date	Jul 28, 2010
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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