

**K083764 AMPHETAMINES II**Feb 3, 2010  
412 days to decisionK083764 · Product code: **DKZ** · Chemistry  
Source: <https://www.510kdatabase.net/k083764/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Dec 18, 2008
Decision date	Feb 3, 2010
Days to decision	412 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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