

K130082 GENPRIME DRUGS OF ABUSE READER SYSTEMDec 20, 2013
340 days to decisionK130082 · Product code: **DKZ** · Chemistry
Source: <https://www.510kdatabase.net/k130082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jan 14, 2013
Decision date	Dec 20, 2013
Days to decision	340 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genprime, Inc.
Location	Oms River, NJ, US
Contact	Maureen Garner
510(k) history	2 submissions · 2 cleared · 2013-2014

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