

K061617 FORSURE ONE STEP DIP & READ (X) DRUG SCREEN TESTNov 22, 2006
166 days to decisionK061617 · Product code: **DKZ** · Chemistry
Source: <https://www.510kdatabase.net/k061617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jun 9, 2006
Decision date	Nov 22, 2006
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tianjin New Bay Bioresearch Co., Ltd.
Location	Carlsbad, CA, US
Contact	RODRIGO BERTIE
510(k) history	11 submissions · 11 cleared · 2005-2013

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