

**K122064 FORSURE ONE STEP BUPRENORPHINE CUP TEST
DEVICE**May 7, 2013
298 days to decisionK122064 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k122064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jul 13, 2012
Decision date	May 7, 2013
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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