

K042990 FOR SURE ONE STEP BUPRENORPHINE TEST STRIPMay 10, 2005
193 days to decisionK042990 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k042990/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 29, 2004
Decision date	May 10, 2005
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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