

**K042988 RAPID ONE STEP BUPRENORPHINE TEST CARD**May 12, 2005  
195 days to decisionK042988 · Product code: **DJG** · Chemistry  
Source: <https://www.510kdatabase.net/k042988/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 29, 2004
Decision date	May 12, 2005
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042988/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 8, 2026