

**K032992 UNIMARK HOME PREGNANCY TEST DEVICE**Nov 21, 2003  
57 days to decisionK032992 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k032992/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 25, 2003
Decision date	Nov 21, 2003
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biotech Atlantic, Inc.</b>
Location	Eatontown, NJ, US
Contact	FRANCIS L DENG
510(k) history	4 submissions · 4 cleared · 1994-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032992/> 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 29, 2026