FDA 510(k) Premarket Notification

K032992 UNIMARK HOME PREGNANCY TEST DEVICE

CLEARED

Nov 21, 2003
57 days to decision

K032992 · 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	**Biotech Atlantic, Inc.**
Location	Eatontown, NJ, US
Contact	FRANCIS L DENG
510(k) history	4 submissions · 4 cleared · 1994-2003