FDA 510(k) Premarket Notification

K992232 FIRST RESPONSE 1-STEP PREGNANCY

CLEARED

Dec 21, 1999
172 days to decision

K992232 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k992232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jul 2, 1999
Decision date	Dec 21, 1999
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Armkel, LLC**
Location	Mchenry, IL, US
Contact	Maureen Garner
510(k) history	68 submissions · 68 cleared · 1979-2004