FDA 510(k) Premarket Notification

# K030258 FIRST RESPONSE PREGNANCY TEST

**CLEARED**

Feb 25, 2003
32 days to decision

K030258 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k030258/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Test, Pregnancy, Hcg, Over The Counter (LCX) |
| Date received | Jan 24, 2003 |
| Decision date | Feb 25, 2003 |
| Days to decision | 32 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Armkel, LLC** |
| Location | Mchenry, IL, US |
| Contact | STEPHEN C KOLAKOWSKY |
| 510(k) history | 68 submissions · 68 cleared · 1979-2004 |