

**K973352 BRAND NAME \*1-STEP PREGNANCY**Oct 27, 1997  
52 days to decisionK973352 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k973352/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Kit, Test, Pregnancy, Hcg, Over The Counter (LCX) |
| Date received         | Sep 5, 1997                                       |
| Decision date         | Oct 27, 1997                                      |
| Days to decision      | 52 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Armkel, LLC</b>                      |
| Location       | Mchenry, IL, US                         |
| Contact        | THERESA SINES                           |
| 510(k) history | 68 submissions · 68 cleared · 1979-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973352/> 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