

**K040866 FIRST RESPONSE ONE-STEP DIGITAL PREGNANCY TEST**

Oct 19, 2004  
200 days to decision

K040866 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k040866/>

**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	Apr 2, 2004
Decision date	Oct 19, 2004
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Armkel, LLC</b>
Location	Mchenry, IL, US
Contact	STEPHEN C KOLAKOWSKY
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/k040866/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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