

**K083716 FIRST RESPONSE EARLY RESULT PREGNANCY TEST (OTC)**Jun 8, 2009  
175 days to decisionK083716 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k083716/>**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	Dec 15, 2008
Decision date	Jun 8, 2009
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Church &amp; Dwight Co., Inc.</b>
Location	Princeton, NJ, US
Contact	STEPHEN C KOLAKOWSKY
510(k) history	29 submissions · 29 cleared · 2006-2025

Church & Dwight Co., Inc. is an American consumer goods company headquartered in Princeton, New Jersey. Founded in 1847, the company manufactures personal care, household, and specialty products under brands including Arm & Hammer, Trojan, OxiClean, and First Response. Church & Dwight has received FDA 510(k) clearances from total submissions since 2006. The company's regulatory focus centers on Obstetrics & Gynecology devices, which represent 86% of submissions. The latest clearance was issued in 2025, reflecting continued regulatory activity. The company's cleared device...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k083716/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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