

K123567 FIRST RESPONSE GOLD DIGITAL PREGNANCY TESTSep 10, 2013
294 days to decisionK123567 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k123567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Nov 20, 2012
Decision date	Sep 10, 2013
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Church & Dwight Co., Inc.
Location	Princeton, NJ, US
Contact	LISA BURNS
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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