

K150063 One Step hCG Pregnancy TestOct 2, 2015
262 days to decisionK150063 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k150063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jan 13, 2015
Decision date	Oct 2, 2015
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coretests, Inc.
Location	Carlsbad, CA, US
Contact	Wen Li
510(k) history	2 submissions · 2 cleared · 2015-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150063/> Data sourced from FDA 510(k) public records (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. - Generated June 3, 2026