

K132085 ONE STEP HCG TEST STRIP, ONE STEP HCG TEST CASSETTE, ONE STEP HCG TEST MIDSTREAMNov 12, 2013
130 days to decisionK132085 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k132085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jul 5, 2013
Decision date	Nov 12, 2013
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Co-Innovation Biotech Co., Ltd.
Location	Guangzhou, Guangdong, CN
Contact	HONG FENG
510(k) history	10 submissions · 10 cleared · 2013-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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