

**K213808 Co-Innovation One Step Human Chorionic  
Gonadotropin (HCG) Test Strip, Co-Innovation One Step Human  
Chorionic Gonadotropin (HCG) Test Cassette, Co-Innovation  
One Step Human Chorionic Gonadotropin (HCG) Test  
Midstream**Apr 5, 2022  
120 days to decisionK213808 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k213808/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Dec 6, 2021
Decision date	Apr 5, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Co-Innovation Biotech Co., Ltd.</b>
Location	Guangzhou, Guangdong, CN
Contact	Hong Feng
510(k) history	10 submissions · 10 cleared · 2013-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213808/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026