

K242135 Synthgene Home Test HCG Test StripJan 31, 2025
193 days to decisionK242135 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k242135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jul 22, 2024
Decision date	Jan 31, 2025
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Synthgene Home Test HCG Test Cassette; Synthgene Home Test HCG Test Midstream

APPLICANT

Company	Nanjing Synthgene Medical Technology Co., Ltd.
Location	Nanjing, CN
Contact	Alvin Qian
510(k) history	1 submissions · 1 cleared · 2025-2025

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