

**K193132 CLUNGENE HCG Pregnancy Rapid Test Cassette,
CLUNGENE HCG Pregnancy Rapid Test Strip, CLUNGENE HCG
Pregnancy Rapid Test Midstream**Dec 11, 2019
29 days to decisionK193132 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k193132/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Nov 12, 2019
Decision date	Dec 11, 2019
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Clongene Biotech Co., Ltd.
Location	Hangzhou, CN
Contact	Zheng Shujian
510(k) history	9 submissions · 9 cleared · 2016-2026

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