

K212418 hCG One Step Pregnancy TestJun 30, 2022
331 days to decisionK212418 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k212418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Aug 3, 2021
Decision date	Jun 30, 2022
Days to decision	331 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Healstone Biotech, Inc.
Location	Vancouver, CA
Contact	Guang Gao
510(k) history	3 submissions · 3 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	Axteria Biomed Consulting
Contact	Guang Gao

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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