

K212447 SEJOY hCG One Step Pregnancy Test Strip, SEJOY hCG One Step Pregnancy Test Cassette, SEJOY hCG One Step Pregnancy Test MidstreamFeb 18, 2022
197 days to decisionK212447 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k212447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Aug 5, 2021
Decision date	Feb 18, 2022
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Location	Hangzhou City, CN
Contact	Yanyan Zhang
510(k) history	1 submissions · 1 cleared · 2022-2022

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