

K243573 FaStep Early Pregnancy Rapid Test StripJan 15, 2025
57 days to decisionK243573 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k243573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Nov 19, 2024
Decision date	Jan 15, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FaStep Early Pregnancy Rapid Test Cassette; FaStep Early Pregnancy Rapid Test Midstream

APPLICANT

Company	Assure Tech., LLC
Location	Wilmington, DE, US
Contact	Allen Chen
510(k) history	5 submissions · 5 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Jenny Xia

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

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