

K233174 FaStep™ Pregnancy Rapid Test StripFeb 5, 2024
130 days to decisionK233174 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k233174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 28, 2023
Decision date	Feb 5, 2024
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FaStep™ Pregnancy Rapid Test Midstream

APPLICANT

Company	Assure Tech. (Hangzhou) Co, Ltd.
Location	Hangzhou, CN
Contact	Shisheng Ling
510(k) history	7 submissions · 7 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	Lsi International
Contact	Joe Shia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233174/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026