

K240643 MissLan® Early Detection Pregnancy Test StripJun 21, 2024
106 days to decisionK240643 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k240643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Mar 7, 2024
Decision date	Jun 21, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MissLan® Early Detection Pregnancy Test Cassette; MissLan® Early Detection Pregnancy Test Midstream

APPLICANT

Company	Guangzhou Decheng Biotechnology Co., Ltd.
Location	Guangzhou, CN
Contact	Weifang Liu
510(k) history	8 submissions · 8 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
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/k240643/> 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