FDA 510(k) Premarket Notification

K222305 MissLan™ Digital Pregnancy Rapid Test

CLEARED

Nov 30, 2022
121 days to decision

K222305 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k222305/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Aug 1, 2022
Decision date	Nov 30, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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**
Contact	Joe Shia

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