

K253662 LIXI (LXOSFM1)

Jul 14, 2026
236 days to decision

K253662 · Product code: MSC · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k253662/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Std, Oral Sex (MSC)
Date received	Nov 20, 2025
Decision date	Jul 14, 2026
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Luwi, LLC
Location	Mount Prospect, IL, US
Contact	Lisa Kinsella
510(k) history	1 submissions · 1 cleared · 2026-2026