FDA 510(k) Premarket Notification

K252260 RELIEEV HSG Catheter (HSG7FA1)

CLEARED

Nov 26, 2025
128 days to decision

K252260 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k252260/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Jul 21, 2025
Decision date	Nov 26, 2025
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Li Medical Corporation , Ltd.**
Location	Xizhi Dist., TW
Contact	Jago Chen
510(k) history	3 submissions · 3 cleared · 2024-2025