

K243421 Lelo Hex Lubricated Natural Rubber Latex CondomMar 7, 2025
123 days to decisionK243421 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Nov 4, 2024
Decision date	Mar 7, 2025
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lelo, Inc.
Location	San Jose, CA, US
Contact	Pavle Sedic
510(k) history	3 submissions · 3 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Insight, Inc.
Contact	Kevin Walls

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

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