FDA 510(k) Premarket Notification

# K241617 Durex Polyisoprene Condom

**CLEARED**

Feb 28, 2025
268 days to decision

K241617 · Product code: **MOL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k241617/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom, Synthetic (MOL) |
| Date received | Jun 5, 2024 |
| Decision date | Feb 28, 2025 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Rb Health (Us), LLC** |
| Location | Parsippany, NJ, US |
| Contact | Matthew Pleus |
| 510(k) history | 14 submissions · 14 cleared · 2019-2025 |