

**K241617 Durex Polyisoprene Condom**Feb 28, 2025  
268 days to decisionK241617 · Product code: **MOL** · Obstetrics & GynecologySource: <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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241617/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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