FDA 510(k) Premarket Notification

**CLEARED**

# K243640 Trojan™ Ultra Ribbed Ecstasy latex condom with lubricant (Trojan™ Ultra Ribbed Ecstasy)

Feb 21, 2025
88 days to decision

K243640 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k243640/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Nov 25, 2024 |
| Decision date | Feb 21, 2025 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Church & Dwight Co., Inc.** |
| Location | Princeton, NJ, US |
| Contact | Lori Kordyban |
| 510(k) history | 29 submissions · 29 cleared · 2006-2025 |

Church & Dwight Co., Inc. is an American consumer goods company headquartered in Princeton, New Jersey. Founded in 1847, the company manufactures personal care, household, and specialty products under brands including Arm & Hammer, Trojan, OxiClean, and First Response. Church & Dwight has received FDA 510(k) clearances from total submissions since 2006. The company's regulatory focus centers on Obstetrics & Gynecology devices, which represent 86% of submissions. The latest clearance was issued in 2025, reflecting continued regulatory activity. The company's cleared device...

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Full Circle Regulatory Consulting, LLC** |
| Contact | Dawn Reilly-O'Dell |

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