

# K240379 TROJAN SIS Synthetic Latex Condom with Silicone Lubricant

Oct 8, 2024  
244 days to decisionK240379 · Product code: **MOL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k240379/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom, Synthetic (MOL)
Date received	Feb 7, 2024
Decision date	Oct 8, 2024
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Church &amp; Dwight Co., Inc.</b>
Location	Princeton, NJ, US
Contact	Lori Barr
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	<b>Full Circle Regulatory Consulting, LLC</b>
Contact	Dawn Reilly-O'Neil

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

## CLINICAL EVIDENCE - NCT05370196

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### Synthetic Male Condom Slippage-Breakage Study

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	600 patients (actual)
Study sites	2 sites
Condition studied	Contraceptive; Sexually Transmitted Diseases
Primary purpose	Prevention
Study type	Interventional
Study design	Crossover
Masking	Triple
Completion date	May 12, 2023
Sponsor	Church & Dwight Company, Inc. (Industry)

### Primary outcome

Total Clinical Failure Rate

### Secondary outcome

## Clinical Breakage Rate

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05370196](https://clinicaltrials.gov/study/NCT05370196)

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k240379/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)), ClinicalTrials.gov (U.S. National Library of Medicine).  
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