

K161545 Trojan XOXO Thin Male Natural Rubber Latex Condom with Silicone and Aloe LubricantAug 26, 2016
84 days to decisionK161545 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k161545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jun 3, 2016
Decision date	Aug 26, 2016
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Church & Dwight Co., Inc.
Location	Princeton, NJ, US
Contact	Lisa Burns
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...

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Device record: <https://www.510kdatabase.net/k161545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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