

K243967 ONE Nitrile CondomApr 8, 2025
106 days to decisionK243967 · Product code: **MOL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k243967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom, Synthetic (MOL)
Date received	Dec 23, 2024
Decision date	Apr 8, 2025
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Global Protection Corp.
Location	Boston, MA, US
Contact	Christina Cataldo
510(k) history	11 submissions · 10 cleared · 1997-2025

CLINICAL EVIDENCE - NCT06079060**Evaluation of Synthetic Nitrile Male Condom Compared to Standard Latex Male Condom**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	305 patients (actual)
Study sites	3 sites
Condition studied	Sexually Transmitted Diseases
Primary purpose	Prevention
Study type	Interventional
Study design	Crossover
Masking	Triple
Completion date	Oct 11, 2024
Sponsor	Karex Industries Sdn. Bhd. (Industry)

Primary outcome**Clinical breakage****Secondary outcome****Genital discomfort**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06079060