

K240896 ONE Nitrile CondomAug 23, 2024
144 days to decisionK240896 · Product code: **MOL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k240896/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom, Synthetic (MOL)
Date received	Apr 1, 2024
Decision date	Aug 23, 2024
Days to decision	144 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 - NCT05912283

Evaluation of 2 Synthetic Nitrile Male Condoms Compared to a Standard Latex Male Condom

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	600 patients (actual)
Study sites	3 sites
Condition studied	Sexually Transmitted Diseases
Primary purpose	Prevention
Study type	Interventional
Study design	Crossover
Masking	Triple
Completion date	Jan 31, 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/NCT05912283
