

K232470 Polyisoprene Extra Large CondomMay 9, 2024
267 days to decisionK232470 · Product code: **MOL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k232470/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom, Synthetic (MOL)
Date received	Aug 16, 2023
Decision date	May 9, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suretex Limited
Location	Tambon Khao Kwai, Amphur Phunphin, TH
Contact	Alison Arnot
510(k) history	6 submissions · 6 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Digangi Consulting, LLC
Contact	Donna DiGangi

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

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