FDA 510(k) Premarket Notification

K231908 45 Micron Polyisoprene Condom

CLEARED

Oct 27, 2023
120 days to decision

K231908 · Product code: **MOL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k231908/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom, Synthetic (MOL)
Date received	Jun 29, 2023
Decision date	Oct 27, 2023
Days to decision	120 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	**C3-Carey Consultants, LLC**
Contact	Carole C. Carey

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