

K221243 OFNat Lubricant (L15)Sep 30, 2022
151 days to decisionK221243 · Product code: **NUC** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k221243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	May 2, 2022
Decision date	Sep 30, 2022
Days to decision	151 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	KC Nguyen
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](https://accessdata.fda.gov)

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