

K241443 Sutil Luxe Personal Lubricant (models 1126, 0009, 0010, 0011)Jan 21, 2025
244 days to decisionK241443 · Product code: **NUC** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k241443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	May 22, 2024
Decision date	Jan 21, 2025
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sutil Luxe Vanilla Personal Lubricant (models 1119, 1120); Sutil Luxe Coconut Personal Lubricant (models 1121, 1122); Sutil Luxe Mint Personal Lubricant (models 1117, 1118)

APPLICANT

Company	Hathor Professional Skincare , Ltd.
Location	Victoria, CA
Contact	Carolyn (Mellta) Swift
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Rob Packard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241443/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026