



January 21, 2025

Hathor Professional Skincare Ltd.  
% Rob Packard  
President  
Medical Device Academy, Inc.  
345 Lincoln Hill Rd  
Shrewsbury, Vermont 05738

Re: K241443  
Trade/Device Name: Sutil Luxe Personal Lubricant (models 1126, 0009, 0010, 0011);  
Sutil Luxe Vanilla Personal Lubricant (models 1119, 1120);  
Sutil Luxe Coconut Personal Lubricant (models 1121, 1122);  
Sutil Luxe Mint Personal Lubricant (models 1117, 1118)  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Received: December 13, 2024

Dear Rob Packard:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -S

For  
Monica Garcia, Ph.D.  
Assistant Director  
DHT3B: Division of Reproductive,  
Gynecology, and Urology Devices  
OHT3: Office of Gastrorenal, ObGyn,  
General Hospital, and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K241443

Device Name

Sutil Luxe Personal Lubricant (models 1126, 0009, 0010, 0011); Sutil Luxe Vanilla Personal Lubricant (models 1119, 1120); Sutil Luxe Coconut Personal Lubricant (models 1121, 1122); Sutil Luxe Mint Personal Lubricant (models 1117, 1118)

Indications for Use (Describe)

Sutil Luxe Personal Lubricant, Sutil Luxe Vanilla Personal Lubricant, Sutil Luxe Coconut Personal Lubricant, and Sutil Luxe Mint Personal Lubricant are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) SUMMARY (K241443)****I. SUBMITTER**

Company Name      Hathor Professional Skincare Ltd.  
Address              P.O Box 23027 Cook St R.P.O  
City, State, Zip      Victoria BC V8T 3S6 Canada  
Tel:                    +1.604.732.7772

Contact Person:      Carolyn (Mellita) Swift / Leonard Krause  
Date Prepared:        January 17, 2025

**II. DEVICE****Device Trade Name / Models:**

- SUTIL LUXE PERSONAL LUBRICANT (Models 1126, 0009, 0010, 0011)
- SUTIL LUXE VANILLA PERSONAL LUBRICANT (Models 1119, 1120)
- SUTIL LUXE COCONUT PERSONAL LUBRICANT (Models 1121, 1122)
- SUTIL LUXE MINT PERSONAL LUBRICANT (Models 1117, 1118)

Common Name:              Personal Lubricant  
Regulation Name:            Condom  
Regulation Number:        21 CFR §884.5300  
Regulatory Class:            Class II  
Product Code:                NUC (lubricant, personal)

**III. PREDICATE DEVICE**

Predicate Manufacturer:    Good Clean Love, Inc.  
Predicate Trade Name:      Desnuda Reflect  
Predicate 510(k):            K211998

The predicate device has not been subject to a design-related recall.

**IV. DEVICE DESCRIPTION**

Sutil Luxe Personal Lubricant, Sutil Luxe Vanilla Personal Lubricant, Sutil Luxe Coconut Personal Lubricant, and Sutil Luxe Mint Personal Lubricant are non-sterile, water-based personal lubricants that are compatible with natural rubber latex and polyisoprene condoms. They are not compatible with polyurethane condoms.

Sutil Luxe Personal Lubricant, Sutil Luxe Vanilla Personal Lubricant, Sutil Luxe Coconut Personal Lubricant, and Sutil Luxe Mint Personal Lubricant are sold as over-the-counter (OTC) products in tube packaging made of low-density polythethylene (outer layer), ethylene vinyl alcohol copolymer (middle layer) and low-density polyethylene (inner layer), ranging from 0.34 fl oz to 8 fl oz, depending on formulation.

These products are composed of purified water, propanediol, oat beta glucan, hyaluronic acid, gluconolactone, sodium benzoate, steviol glycosides, and Nelumbo Nucifera (Lotus) Root water. Depending on the formulation, the flavored formulations contain natural vanilla 1.5X flavor extract, organic coconut flavor concentrate, or organic mint flavor concentrate.

The device specifications are listed in Table 1 below:

Table 1: Device Specifications for Sutil Luxe Personal Lubricant, Sutil Luxe Vanilla Personal Lubricant, Sutil Luxe Coconut Personal Lubricant, and Sutil Luxe Mint Personal Lubricant

| Parameter                                                                                                                                                                                             | Test Method  | Specification                                                                                                                                                                                                                                                  |                           |                           |                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------|---------------------------|
|                                                                                                                                                                                                       |              | Sutil Luxe                                                                                                                                                                                                                                                     | Sutil Luxe Vanilla        | Sutil Luxe Coconut        | Sutil Luxe Mint           |
| Appearance                                                                                                                                                                                            | Visual       | Viscous liquid                                                                                                                                                                                                                                                 | Viscous liquid            | Viscous liquid            | Viscous liquid            |
| Color                                                                                                                                                                                                 | Visual       | Clear                                                                                                                                                                                                                                                          | Brownish                  | Off-white                 | Off-white                 |
| Odor                                                                                                                                                                                                  | Organoleptic | No scent                                                                                                                                                                                                                                                       | Vanilla                   | Coconut                   | Mint                      |
| pH                                                                                                                                                                                                    | USP <791>    | 4.0-5.0                                                                                                                                                                                                                                                        |                           |                           |                           |
| Viscosity (cps)                                                                                                                                                                                       | USP <911>    | 900-5,000                                                                                                                                                                                                                                                      | 900-8,000                 | 900-5,500                 | 900-5000                  |
| Osmolality (mOsm/kg)                                                                                                                                                                                  | USP<785>     | 675-825<br>(1:4 dilution)                                                                                                                                                                                                                                      | 750-900<br>(1:4 dilution) | 725-875<br>(1:4 dilution) | 725-875<br>(1:4 dilution) |
| Antimicrobial Effectiveness                                                                                                                                                                           | USP <51>     | Meets USP <51> criteria for category 2.<br>Bacteria: No less than 2.0 log reduction from initial count at 14 days, and no increase from the 14-day count at 28 days.<br>Yeast and Molds: No increase from the initial calculated count at 14 days and 28 days. |                           |                           |                           |
| Total Microbial Count (TAMC)                                                                                                                                                                          | USP <61>     | <100 cfu/g                                                                                                                                                                                                                                                     |                           |                           |                           |
| Fungal/Yeast/Mold Limits (TYMC)                                                                                                                                                                       | USP <61>     | <10 cfu/g                                                                                                                                                                                                                                                      |                           |                           |                           |
| Absence of Pathogenic Organisms ( <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Salmonella</i> , <i>Escherichia coli</i> , <i>Clostridium species</i> , <i>Candida albicans</i> ) | USP <62>     | Absent                                                                                                                                                                                                                                                         |                           |                           |                           |

## V. INDICATIONS FOR USE

Sutil Luxe Personal Lubricant, Sutil Luxe Vanilla Personal Lubricant, Sutil Luxe Coconut Personal Lubricant, and Sutil Luxe Mint Personal Lubricant are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.

## VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the intended use and technological characteristics of the subject and predicate devices:

|                          | Subject Devices (K241443)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Predicate Device (K211998)                                                                                                                                                                                                                                                                                                                                                |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indications for Use      | Sutil Luxe Personal Lubricant, Sutil Luxe Vanilla Personal Lubricant, Sutil Luxe Coconut Personal Lubricant, and Sutil Luxe Mint Personal Lubricant are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.                                                                                                                                                                                                                                                                                                                            | Desnuda Reflect is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Rx/OTC                   | OTC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | OTC                                                                                                                                                                                                                                                                                                                                                                       |
| Water-based              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Yes                                                                                                                                                                                                                                                                                                                                                                       |
| Ingredients              | <p>Sutil Luxe – Water, Propanediol, Hyaluronic Acid, Nelumbo Nucifera Root Water (Lotus Root), Beta-Glucan (Oat), Gluconolactone, Sodium Benzoate.</p> <p>Sutil Luxe Vanilla – Water, Propanediol, Hyaluronic Acid Sodium, Natural Vanilla 1.5X Flavor Extract, Nelumbo Nucifera Root Water (Lotus Root), Beta-Glucan (Oat), Steviol Glycosides, Gluconolactone, Sodium Benzoate.</p> <p>Sutil Luxe Coconut – Water, Propanediol, Organic Coconut Flavor Concentrate, Hyaluronic Acid Sodium, Nelumbo Nucifera Root Water (Lotus Root), Beta-Glucan (Oat), Steviol Glycosides, Gluconolactone, Sodium Benzoate.</p> <p>Sutil Luxe Mint – Water, Propanediol, Organic Mint Flavor Concentrate, Hyaluronic Acid Sodium, Nelumbo Nucifera Root Water (Lotus Root), Beta-Glucan (Oat), Steviol Glycosides, Gluconolactone, Sodium Benzoate.</p> | Water, Hyaluronic Acid, Hydroxyethylcellulose, Xanthan Gum, Zemea Propanediol, Sodium Benzoate, Potassium Sorbate, DL Lactic Acid                                                                                                                                                                                                                                         |
| Sterile                  | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No                                                                                                                                                                                                                                                                                                                                                                        |
| Condom Compatibility     | Natural Rubber Latex and Polyisoprene Condoms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Natural Rubber Latex and Polyisoprene Condoms                                                                                                                                                                                                                                                                                                                             |
| Shelf Life               | 2 years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 1 year                                                                                                                                                                                                                                                                                                                                                                    |
| Physical Characteristics | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Yes                                                                                                                                                                                                                                                                                                                                                                       |

|                                                                       |     |     |
|-----------------------------------------------------------------------|-----|-----|
| Tested (appearance, color, odor)                                      |     |     |
| pH Tested                                                             | Yes | Yes |
| Osmolality Tested                                                     | Yes | Yes |
| Biocompatibility Tested                                               | Yes | Yes |
| Microbiology Tested (absence of pathogenic organisms, TAMC, and TYMC) | Yes | Yes |
| Antimicrobial Effectiveness Tested                                    | Yes | Yes |

The subject and predicate device have the same intended use (i.e., provides lubrication during intimate sexual activity). The subject and predicate device have different technological characteristics, including variations in formulations, specifications, and shelf-life durations. The differences in the technological characteristics of the subject and predicate do not raise different questions of safety and effectiveness.

## VII. SUMMARY OF PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

### Shelf-life Testing

The subject devices have a 2-year shelf-life based on the results of real-time aging. Testing on samples showed that the subject devices met all device specifications listed in Table 1 above across the device shelf-life.

### Biocompatibility Testing

Biocompatibility testing was performed in accordance with the 2023 FDA guidance document “Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process”, as follows:

- Cytotoxicity per ISO 10993-5:2009
- Skin Irritation and Sensitization – Human Repeat Insult Patch Test (HRIPT), an alternative test method to ISO 10993-10:2021 and ISO 10993-23:2021
- Acute Systemic Toxicity per ISO 10993-11:2017

The results of this testing demonstrate that the subject lubricants are non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

### Condom Compatibility

The compatibility of the subject devices with condoms was evaluated in accordance with ASTM D7661-18, “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms” and were determined to be compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms.

## VIII. CONCLUSIONS

The results of the performance testing described above demonstrate that Sutil Luxe Personal Lubricant, Sutil Luxe Vanilla Personal Lubricant, Sutil Luxe Coconut Personal Lubricant, and Sutil Luxe Mint Personal Lubricant are as safe and effective as the predicate device and support a determination of substantial equivalence.