June 9, 2026

Hathor Professional Skincare Ltd.
% Gregory Chrysler
Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Rd
Sherwsbury, Vermont 05738

Re: K252914
Trade/Device Name: Sutil Pure Personal Lubricant (Models 1148, 1145, 1146, 1147)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 8, 2025
Received: September 12, 2025

Dear Gregory Chrysler:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252914

Device Name
Sutil Pure Personal Lubricant (Models 1145, 1146, 1147, 1148)

Indications for Use *(Describe)*
Sutil Pure Personal Lubricant (Models 1145, 1146, 1147, 1148) 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. The product is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY (K252914)

I. SUBMITTER

Company Name Hathor Professional Skincare Ltd.
Address 2618 Roseberry Ave.
City, State, Zip Victoria, BC V8R 3T7 Canada
Tel: +1.778.679.0037

Contact Person: Carolyn (Mellta) Swift
Date Prepared: May 21, 2026

II. DEVICE

Device Trade Name / Models: SUTIL PURE PERSONAL LUBRICANT (Models 1145, 1146, 1147, 1148)
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

Manufacturer: Hathor Professional Skincare Ltd.
Trade Name: SUTIL RICH PERSONAL LUBRICANT (Models 1127, 0012, 0013, 0014)
510(k): K241443

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

IV. DEVICE DESCRIPTION

Sutil Pure Personal Lubricant (Models 1145, 1146, 1147, 1148) 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 Pure Personal Lubricant (Models 1145, 1146, 1147, 1148) is 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.

The product is composed of purified water, propanediol, lactobacillus ferment, hyaluronic acid, and oat beta glucan.

The device specifications are listed in Table 1 below:

Table 1: Device Specifications for Sutil Pure Personal Lubricant (Models 1145, 1146, 1147, 1148)

Parameter	Test Method	Sutil Pure Specification

Appearance	Visual	Very viscous liquid
Color	Visual	Clear
Odor	Organoleptic	No scent
pH	USP <791>	4.0 – 5.0
Viscosity (cps)	USP <911>	30,000 – 40,000 cps
Osmolality (mOsm/kg)	USP<785>	550 – 700 mOsm/kg (1:5 dilution)
Antimicrobial Effectiveness	USP <51>	Meets USP<51> criteria for category 2. 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. 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 (*Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella, Escherichia coli, Candida albicans*)	USP <62>	Absent

V. INDICATIONS FOR USE

Sutil Pure Personal Lubricant (Models 1145, 1146, 1147, 1148) 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. The product is 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 Device (K252914)	Predicate Device (K241443)
Indications for Use	Sutil Pure Personal Lubricant (Models 1145, 1146, 1147, 1148) 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. The product is not compatible with polyurethane condoms.	Sutil Rich Personal Lubricant 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. The product is not compatible with polyurethane condoms.
Rx/OTC	OTC	OTC
Water-based	Yes	Yes
Ingredients	Water, Propanediol (bio 1,3-propanediol), Lactobacillus Ferment, Hyaluronic Acid Sodium, Oat Beta Glucan Liquid.	Water, Propanediol (bio 1,3-propanediol), Hyaluronic Acid, D-Glucono-1,5-lactone, Sodium Benzoate, Nelumbo Nucifera Root

		Water, Horny Goat (Epimeduim Sagittatum) Herb, Organic Siberian Ginseng (Eleuthero) Std. Extract, Jujube (Zizyphus Jujuba) Fruit Powder Extract
Sterile	No	No
Condom Compatibility	Natural Rubber Latex and Polyisoprene Condoms	Natural Rubber Latex and Polyisoprene Condoms
Shelf Life	6 months	2 years
Physical Characteristics Tested (appearance, color, odor)	Yes	Yes
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 device has a 6-month shelf-life based on the results of a real-time aging study. 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
- Sensitization (GPMT) per ISO 10993-10:2021
- Vaginal Irritation per ISO 10993-23:2021
- Acute systemic toxicity per ISO 10993-11:2017

The results of this testing demonstrate that the subject lubricants are moderately 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 Pure Personal Lubricant (Models 1145, 1146, 1147, 1148) is as safe and effective as the predicate device and support a determination of substantial equivalence.