



September 30, 2022

Suretex Limited
% Carole C. Carey
Senior Consultant
C3-Carey Consultants, LLC
9451 Ellsworth Court
Fulton, MD 20759

Re: K221243
Trade/Device Name: OFNat Lubricant (L15)
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 31, 2022
Received: September 1, 2022

Dear Carole C. Carey:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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)

K221243

Device Name

OFNat Lubricant (L15)

Indications for Use (Describe)

OFNat Lubricant (L15) is a personal lubricant for vaginal and penile 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.

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
K221243
OFNat Lubricant (L15)

1. Submitter Information

Applicant: Suretex Limited
Contact: KC Nguyen, Vice President, R&D, QA and RA
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Tambon Khao Hua Kwai, Amphur Phunphin
Suratthani 84130 Thailand
Phone: +66 77 277 400
Email: kc.nguyen@lifestyles.com

2. Correspondent Information

Correspondent firm: C3-Carey Consultants, LLC
Contact: Carole Carey
Address: 9451 Ellsworth Court, Fulton, MD 20759 USA
Phone: (301) 395-2249
Email: carolecarey@mac.com

3. Date prepared: September 27, 2022

4. Subject Device Information

Device Trade Name: OFNat Lubricant (L15)
Common Name: Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: NUC (lubricant, personal)
Device Class: Class II

5. Predicate Device Information

Device Name: Lifestyles Natural Personal Lubricant
510(k) Number: K122054
Manufacturer: Ansell Healthcare Products LLC

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

6. Device Description

OFNat Lubricant (L15) is a non-sterile, water-based personal lubricant for vaginal and penile application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms.

Its formulation consists of water (aqua), propanediol, okra extract, hydroxyethylcellulose, sodium lactate, benzoic acid, and flaxseed gum.

OFNat Lubricant (L15) is sold as an over-the-counter (OTC) product and is packaged in 80 ml black HDPE bottle and 5 ml sachet.

Device specifications for the OFNat Lubricant (L15) are listed in Table 1.

Table 1: Device Specifications for OFNat Lubricant (L15)

Property	Specification
Appearance	Semi-Viscous liquid
Color	Clear
Odor	Odorless
Viscosity (per USP<911>)	2,200 – 3,500 cps
pH (per USP<791>)	3.8 – 4.5
Osmolality (per USP<785>)	3,100 – 4,100 mOsm/kg
Total Aerobic Microbial Count (TAMC, per USP <61>)	<100 cfu/g
Total Yeast and Mold Count (TYMC, per USP <61>)	<10 cfu/g
Presence of Pathogens (per USP <62>)	Specification
<i>Pseudomonas aeruginosa</i>	Absent
<i>Staphylococcus aureus</i>	Absent
<i>Candida albicans</i>	Absent
<i>Escherichia coli</i>	Absent
<i>Salmonella spp.</i>	Absent
<i>Clostridia spp</i>	Absent
Antimicrobial Effectiveness Testing (per USP <51>)	Specification
<i>Bacteria</i>	Meets USP <51> criteria for category 2. No less than 2.0 log reduction from initial count at 14 days and no increase from the 14-day count at 28 days
<i>Yeast and Molds</i>	No increase from the initial calculated count at 14 and 28 days

7. Indications for Use

OFNat Lubricant (L15) is a personal lubricant for vaginal and penile 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.

8. 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 device.

Table 2: Intended Use and Technological Characteristics Comparison of the Subject and Predicate Device

	OFNat Lubricant (L15) K221243 Subject Device	LifeStyles® Natural Personal Lubricant K122054 Predicate Device
Indications for Use	OFNat Lubricant (L15) is a personal lubricant for vaginal and penile 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.	Lifestyles(r) natural 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, polyurethane, and polyisoprene condoms.
Base type	Water	Water
Primary ingredients	Water (Aqua), Propanediol, Okra Extract, Hydroxyethylcellulose, Sodium Lactate, Benzoic Acid, Flaxseed Gum	Water (Aqua), Glycerin, Xanthan Gum, Sodium Hyaluronate, Potassium Sorbate, Sorbic Acid, Sodium Chloride
Rx/OTC	OTC	OTC
Sterile	No	No
Appearance	Semi-Viscous liquid	--
Color	Clear	--
Odor	Odorless	--
Viscosity	2,200 – 3,500 cps	--
pH	3.8 – 4.5	--
Osmolality	3,100 – 4,100 mOsm/Kg	--
Total Aerobic Microbial count (TAMC)	<100 cfu/g	--
Total Yeast and Mold Count (TYMC)	<10 cfu/g	--
Absence of Pathogenic Organisms	Yes	Yes
Antimicrobial Effectiveness Tested	Yes	Yes
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms	Compatible with natural rubber latex, polyisoprene, and polyurethane condoms
Biocompatibility Tested	Yes	Yes
Shelf life	17 months	36 months

The subject and predicate device indications for use and intended use are the same. The subject and predicate device have different technological characteristics, including formulations, shelf-life, and condom compatibility. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing was performed in accordance with the 2020 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."* The following testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing support the biocompatibility of the device materials.

Shelf-Life

The subject device has a shelf-life of 17 months. Results from accelerated aging demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

The compatibility of OFNat Lubricant (L15) with condoms was evaluated in accordance with ASTM D7661-10(R) 2017 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." The results of this test showed OFNat Lubricant (L15) to be compatible with natural rubber latex and polyisoprene condoms. OFNat Lubricant (L15) is not compatible with polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that OFNat Lubricant (L15) is as safe and effective as the predicate device and supports a determination of substantial equivalence.