September 10, 2018

Necessaire, Inc.
% Louie Goryoka
Regulatory Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K181078
Trade/Device Name: The Sex Gel
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 8, 2018
Received: July 16, 2018

Dear Louie Goryoka:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181078

Device Name
The Sex Gel

Indications for Use *(Describe)*
The Sex Gel 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 latex, polyisoprene, and 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
The Sex Gel

Company Name: Necessaire, Inc.

Company Address: 10 Arbolado Court
Manhattan Beach, California 90266
Contact Number: Phone: (512) 560-5750
Email: randi@necessaireinc.com

Contact Person: Louie Goryoka – Regulatory & Quality Consultant
Med-Device Consulting, Inc.
Phone: (818) 735-0488
Email: mdci@m-dci.us

Summary Preparation Date: August 17, 2018

Device Trade Name:	The Sex Gel
Common Name:	Personal Lubricant
Classification Name(s):	Condom
Classification Regulation:	21 CFR §884.5300 (Condom)
Product Code:	NUC (lubricant, personal)
Device Class:	Class II

Predicate Devices	Aqua Lube Natural Lubricants Personal Lubricant
510(k) Number:	K130345
Manufacturer:	Mayer Laboratories, Inc.
Product Code:	NUC
Device Class:	Class II

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

Device Description

The Sex Gel is a non-sterile, water-based, over-the-counter personal lubricant, formulated to be a clear liquid. The device contains a blend of ingredients similar to ingredients found in the predicate device.

The device is designed to supplement the body's own natural lubrication fluids and is compatible for use with or without natural rubber latex, polyisoprene, or polyurethane condoms during intimate sexual activity. The device formula is neither a contraceptive nor a spermicide.

The product is packaged in (50 ml / 1.7 oz) bottles made from high density polypropylene (POLY WHITE P 8555). The bottle is fitted with a pump for dispensing lubricant made of polypropylene, butyl, and steel. Each bottle is packaged in a paperboard carton, which constitutes the device's individual carton.

The device specifications are listed in the table below:

Table 1: Device Specifications for The Sex Gel Personal Lubricant

Property	Specification
Appearance	Clear to slightly hazy
Color	Colorless

510(K) SUMMARY
The Sex Gel

Odor	Characteristic
Viscosity (cps)	3,000 cps – 5,000 cps
Specific Gravity	1.01 to 1.06
pH	4.0 to 5.0
Osmolality	435 to 535 mOsm/kg
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<10 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Presence of Pathogens per USP <62>	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella	Absent
E. Coli	Absent
Candida albicans	Absent

Indications for Use
The Sex Gel 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, polyisoprene and polyurethane condoms.

Predicate Device Comparison:
The table below lists the comparative intended use and technological characteristics of the subject and predicate device.

Table 2: Comparator Table for Subject Device – The Sex Gel Personal Lubricant and Predicate Device Aqua Lube Natural Lubricants Personal Lubricant.

Characteristic/Feature	**The Sex Gel Lubricant (K181078)**	**Aqua Lube Natural Lubricants Personal Lubricant (k) number K130345**
Indications for Use	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 and polyurethane condoms.	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. It is not compatible with polyurethane condoms.

510(K) SUMMARY
The Sex Gel

Water Based	Yes	Yes
Primary ingredients	Water, aloe barbadensis leaf juice, sorbitol, hydroxyethylcellulose, allantoin, lactic acid / tocopherols (vitamin E), sodium hyaluronate, sodium benzoate & potassium sorbate	Water, aloe, hydroxyethylcellulose, sorbitol, and tocopherols (vitamin E).
Over-the-Counter Use	Yes	Yes
Labeled condom compatible	Yes	Yes
compatible with latex and polyisoprene condoms	Yes	Yes
compatible with polyurethane condoms	Yes	No
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
The product is not a contraceptive and does not contain spermicide	Yes	Yes
Sterile	No	No
Shelf life	6 months	Three years

The subject and predicate device have the same intended use - for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The Sex Gel contains similar ingredients to other cleared lubricants, including the predicate device. However, the subject and predicate device have slightly different formulations and different shelf life. These differences do not raise different types of safety and effectiveness questions. Performance testing, as described below, was utilized to demonstrate the subject device is as safe and effective as the predicate device.

Summary of Performance Data:

Biocompatibility

The device contact duration with the user is A-limited <24 hours, per ISO 10993-1:2009.

Independent third-party laboratories conducted biocompatibility studies on the subject device. These included Acute Systemic Toxicity, Vaginal Irritation Testing, Penile Irritation Testing, Cytotoxicity and Sensitization testing; each were performed in accordance with 2016 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" and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO Direct Contact Method, ISO 10993-5:2009)
- Sensitization (ISO Guinea Pig Maximization Sensitization, ISO 10993-10:2010)

- Vaginal Irritation (ISO Vaginal Irritation Study in Rabbits, ISO 10993-10:2010)
- Penile Irritation (ISO Penile Irritation Study in Rabbits, ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO Tests for Systemic Toxicity, ISO 10993-11:2006)

The results of testing demonstrated the subject device is not cytotoxic, not sensitizing, not irritating and is not acutely systemically toxic.

Condom Compatibility

Condom compatibility testing was performed per ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" on three marketed brands of natural rubber latex condoms, one brand of polyisoprene condoms, and one brand of polyurethane condoms. Results demonstrated the Sex Gel is compatible with natural latex, polyisoprene, and polyurethane condoms.

Shelf Life Testing

The Sex Gel Personal lubricant is shown to have a 6 months shelf life utilizing Arrhenius Equation, as detailed according to ASTM F1980-15 for Accelerated Aging. Testing on samples at accelerated aging showed that the subject device met all device specifications.

Conclusion

The subject device has the same intended use as the predicate device: to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The subject device has similar technological characteristics as the predicate device, as described in the table above. Differences in technological characteristics between the subject and predicate device were evaluated through performance testing, which included biocompatibility, shelf-life and condom compatibility testing. Performance testing demonstrated that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate.