December 13, 2019

FemmePharma Consumer Healthcare, LLC
% Stuart Goldman
Sr. Consultant, RA/QA
Emergo by UL
2500 Bee Cave Road, Bldg. 1, Suite 300
Austin, TX 78746

Re: K190752
Trade/Device Name: Satisfaite
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 14, 2019
Received: November 15, 2019

Dear Stuart Goldman:

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,

for Sharon M. Andrews
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190752

Device Name
Satisfaite™

Indications for Use *(Describe)*
Satisfaite™ is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to supplement the body's natural lubrication, and to enhance the ease and comfort of intimate sexual activity. This product is compatible with natural rubber, latex, and polyisoprene condoms; and 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
Satisfaite™

1. Submission Sponsor

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2. Submission Correspondent

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Email: Stuart.Goldman@UL.com

3. Date Prepared

December 12, 2019

4. Device Identification

Trade/Proprietary Name: Satisfaite™
Common/Usual Name: Personal Lubricant
Classification Name: Condom
Regulation Number: 21 CFR 884.5300
Product Code: NUC
Class: II
Classification Panel: Obstetrics/Gynecology

5. Predicate Device Identification

Replens™ Long-Lasting Vaginal Moisturizer (in 35g Tube with Reusable Applicator) – K101098. The predicate device has not been subject to a design related recall.

6. Device Description

Satisfaite™ is a topically applied, water-based personal lubricant for vaginal application, intended to moisturize and lubricate, and to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Satisfaite™ is self-administered to the vaginal area of the user via a prefilled unit dose applicator for intravaginal administration.

The following features, characteristics and properties are applicable to Satisfaite™:

a. The device consists of the polypropylene plastic applicator pre-filled with the lubricant. The three main ingredients of the lubricant by percent weight are purified water, glycerin and propylene glycol. Each pre-filled applicator holds 1 gram of lubricant and is for a single use in a home environment.

b. Each pre-filled applicator is individually over-wrapped with a disposable polypropylene sleeve and packaged 10 units to a cardboard box.

c. The lubricant makes direct patient contact with the vaginal mucosa and has a contact duration of < 24 hours. The applicator also makes direct patient contact with the vaginal mucosa only at the time of application and is discarded after use.

d. Specifications for the lubricant include the following:

   i. Appearance: Thick gel

   ii. Color: Off-white

   iii. Odor: Characteristic

   iv. pH@ 25°C: 3.8 - 4.6

   v. viscosity: 53,000 – 152,000 cP

   vi. osmolality: 2,300 – 2,800 mOsm/kg

   vii. antimicrobial effectiveness: Meets USP <51> acceptance criteria for Category 2 products

   viii. total microbial count: < 10 cfu/ g

   ix. fungal/yeast /mold limits: < 10 cfu/g

   x. absence of pathogenic organisms: Absence confirmed

7. Indications for Use

Satisfaite™ is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to supplement the body’s natural lubrication, and to enhance the ease and comfort of intimate sexual activity. This product is compatible with natural rubber, latex, and polyisoprene condoms; and is not compatible with polyurethane condoms.

8. Comparison of Technological Characteristics

The subject and predicate devices have similar indications for use except for condom compatibilities. This change does not represent a new intended use. The subject and predicate devices have different technological characteristics, including different formulations, packaging, specifications, and condom compatibilities. The different technological characteristics of the subject devices does not raise different types of safety and effectiveness questions. **Table 5-1** compares Satisfaite™ to Replens™ with respect to its indications for use and technological characteristics.

Table 5-1 –Comparison of Satisfaite™ vs. Replens®

Attributes	Subject Device	Predicate Device	Similarities / Differences
Device Name	Satisfaite™	Replens® Long-Lasting Vaginal Moisturizer	-
Manufacturer	FemmePharma Consumer Healthcare, LLC	Lil Drug Store Products, Inc.	-
510(k)	K190752	K101098	-
Product Code	NUC	NUC	Same
Regulation	§884.5300	§884.5300	Same
Class	II	II	Same
Review Panel	OBGYN	OBGYN	Same
Indications for Use	Satisfaite™ is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to supplement the body's natural lubrication, and to enhance the ease and comfort of intimate sexual activity. This product is compatible with natural rubber, latex, and polyisoprene condoms; and is not compatible with polyurethane condoms.	Replens® is a personal lubricant for 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 condoms and synthetic (polyurethane and polyisoprene) condoms.	The subject device is not compatible with polyurethane condoms while the predicate device is compatible with polyurethane condoms, and this is clearly stated in the product labeling for the subject and predicate devices.
List of Ingredients	Purified water, glycerin, propylene glycol, hydroxyethylcellulose, sodium hyaluronate, hydrochloric acid, methylparaben, vitamin E	Purified water, glycerin, mineral oil, polycarbophil, carbomer homopolymer type b, hydrogenated palm oil glyceride, methylparaben, sorbic acid, sodium hydroxide	Similar
Area of Use	Vagina	Vagina	Same
Packaging Unit	Ten (10) prefilled vaginal applicators per box.	35g tube of gel (enough for 14 applications) + 1 reusable vaginal applicator per box.	Similar – the subject and predicate device are both administered via a plastic vaginal applicator.
Dosage	1 gram per applicator.	2.5 grams per application.	Similar

Prescription / OTC	OTC	OTC	Same
Sterility	Non-Sterile	Non-Sterile	Same
Color	Off-white	Off-white	Same
pH	3.8 - 4.6	2.9	The subject device measured pH is within the normal range of vaginal pH (4.0 – 5.0).
Specific Gravity	0.98 - 1.08	1.02	Similar
Viscosity	53,000 – 152,000 cP	70,000 cP	Similar
Osmolality	2,300 – 2,800 mOsm/kg	1,177 mOsm/kg	Similar
Microbiological Examination USP <61>	Conforms with USP <61> for TAMC	Conforms with USP <61>	Similar
	Conforms with USP <61> for TYMC	Conforms with USP <61>	Similar
Antimicrobial Effectiveness USP <51>	Conforms with USP <51>	Conforms with USP <51>	Similar
Biocompatibility ISO 10993-1	ISO 10993-5 ISO 10993-10 ISO 10993-11	Conforms with ISO 10993-1 and its applicable parts.	Same
Condom compatibility ASTM D7661-10	Compatible with natural rubber latex, and polyisoprene condoms. NOT compatible with polyurethane condoms	Compatible with natural rubber latex, polyisoprene, and polyurethane condoms.	The subject device is not compatible with polyurethane condoms, while the predicate is compatible.

The differences in technological characteristics between Satisfaite™ and Replens™ do not raise different questions of safety and effectiveness.

9. Non-Clinical Performance Data

As part of demonstrating substantial equivalence of Satisfaite™ to Replens®, FemmePharma Consumer Healthcare submitted their device for testing in accordance with the applicable parts of the following voluntary standards. Results confirm that the design inputs and performance specifications for the device are met. Satisfaite™ passed all testing in accordance with the standards shown below, and therefore its substantial equivalence to the predicate devices:

- Condom Compatibility (ASTM D7661-10)
    - testing showed that Satisfaite™ is compatible with:
        - natural rubber latex condoms
        - polyisoprene condoms
    - testing showed that Satisfaite™ is not compatible with:
        - polyurethane condoms
- Biocompatibility studies, including Cytotoxicity, Sensitization, Vaginal Irritation, and Acute Systemic Toxicity Testing were performed in accordance with the 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 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

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

- Microbial - Total Aerobic Microbial Count (USP <61>)
  - testing met the requirements of the standard and demonstrated the device met specifications
- Microbial - Total Combined Yeast/Mold Count (USP <61>)
  - testing met the requirements of the standard and demonstrated the device met specifications
- Microbial - Antimicrobial Effectiveness (USP <51>)
  - testing met the requirements of the standard and demonstrated the device met specifications
- Microbial – Absence of Pathogenic Organism (USP 61/62)
  - testing met the requirements of the standard and demonstrated the device met specifications

10. Conclusion

The results of the non-clinical testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.