July 16, 2019

Fairhaven Health, LLC
Suzanne Munson
VP of Product Development/Compliance
1410 11th St
Bellingham, WA 98225

Re: K190150
Trade/Device Name: Sage 2-in-1 Personal Lubricant and Moisturizer™
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 6, 2019
Received: June 17, 2019

Dear Suzanne Munson:

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 Andrews
Assistant Division 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)*
K190150

Device Name
Sage 2-in-1 Personal Lubricant and Moisturizer™

Indications for Use *(Describe)*
Sage 2-in-1 Personal Lubricant and Moisturizer is 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 condoms. This product is not compatible with polyisoprene or 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- K190150
Sage 2-in-1 Personal Lubricant and Moisturizer™

Submitter:
Applicant: Fairhaven Health, LLC
1410 11th Street
Bellingham, WA 98225

Telephone: 360-543-7888
Email: suzanne@fairhavenhealth.com
Contact Person: Suzanne Munson

Date Prepared: July 15, 2019

Device Information:

Device Name	Sage 2-in-1 Personal Lubricant and Moisturizer ™
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (Lubricant, Personal)
Regulatory Class:	II

Predicate Devices
Good Clean Love Bio-pHresh (K162207) manufactured by Good Clean Love, Inc Eugene, OR.

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

Indications for Use
Sage 2-in-1 Personal Lubricant and Moisturizer is 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 condoms. This product is not compatible with polyisoprene or polyurethane condoms

Description of Device
Sage 2-in-1 Personal Lubricant and Moisturizer™ is a non-sterile, water-soluble personal lubricant for over-the-counter (OTC) use. The lubricant will be provided in a 1.6 oz tube and will also be supplied with a low-density polyethylene applicator.
The device specifications are listed in the table below:

Parameter	Test Method	Specification
Appearance	Visual inspection	Opaque Gel
Odor	Odor via smell of gel	Slight rose and sage odor
pH	USP <791>	4.25-5.5
Viscosity	USP <91>	3000-12000cps
Osmolality	USP <785>	240-370 mOsmo/kg
Antimicrobial Effectiveness	USP <51>	Bacteria: Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days Yeast and Molds: No increase at 14 and 28 relative to initial count.
Total Aerobic Microbial Count (TAMC)	USP <61>	< 100 cfu/ml
Total Fungal/Yeast/Mold Limits (TYMC)	USP <61>	< 10 cfu/ml
Absence of Pathogenic Organisms (*P.aeruginosa, S. aureus, E. Coli, Salmonella* sp., *C. albicans*)	USP <62>	Absent

Summary of technological characteristics compared to predicate device:

Subject & Predicate Devices:	K190150 Subject Device	K162207 Predicate Device
General Device Characteristics		
Personal Lubricant		
Sponsor	Fairhaven Health LLC	Good Clean Love
Indication for Use Statement	Sage 2-in-1 Personal Lubricant and Moisturizer is 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 condoms. This product is not compatible with polyisoprene	Good Clean Love BIO-pHRESH 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

	or polyurethane condoms.	natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms
Regulation Number Product Code Device Class	884.5300	884.5300
Condom Compatibility	Natural rubber latex	Natural rubber latex and polyisoprene
Base Type	Water based	Aloe vera (water based)
Formulation	Purified Water Hypromellose (HPMC) Carbomer homopolymer type b Phenethyl alcohol Caprylyl glycol Salvia Sclarea Sodium Chloride L-Lactic Acid d-Xylose Sodium Hydroxide Monobasic Sodium Phosphate anhydrous Potassium Phosphate anhydrous	Aloe Vera Xanthan Potassium Sorbate Sodium Benzonate
Characteristics		
pH	4.25-5.5	-
Viscosity	3000-12000 Cps	-
Osmolality	240-370 mOsm/kg	-
Antimicrobial Effectiveness	Bacteria: Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days Yeasts and Mold: No increase at 14 and 28 relative to initial count.	Category 2 (Products for mucosal application). Bacteria >=2.0 log reduction at day 14 relative to initial count. No increase at day 28 relative to day-14 count. Yeasts and Mold: No increase at 14 and 28 relative to initial count.
Total Microbial Count	< 100 cfu/g	<10 cfu/g
Fungal/Yeast/Mold Limits	<10 cfu/g	< 10 cfu/g
Absence of Pathogenic Organisms	Absent	Absent
Applicator	Yes	Yes

The subject and predicate devices have same indications for use statements with the exception of the types of condoms they are compatible with. The difference in condom compatibility type do not impact the overall intended use of these devices, which is the same (i.e., lubrication during intimate sexual activity).

The subject and predicate devices have similar technological characteristics (e.g., base type, osmolality, packaging, etc.); however, differences in specifications and formulation exist.

The differences in technological characteristics described above between the subject and predicate devices do not raise different questions of safety and effectiveness. In addition, the specifications for the subject device are comparable to other devices of this type.

Summary of non-clinical performance testing:

Biocompatibility:
Biocompatibility studies of the lubricant and applicator 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 10993-11:2006) – this test only conducted on the personal lubricant component

Condom Compatibility:
Condom compatibility testing was performed in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." The results of testing demonstrated that the subject device is compatible with natural rubber latex condoms and is not compatible with polyisoprene and polyurethane condoms.

Shelf-Life:
The shelf-life of the device is 16 months in accordance with the results of an accelerated aging study. All device specifications (see table on page 2 of this summary) were met at all timepoints assessed (equivalent to 0-16 months of real-time aging).

Substantial Equivalence:
The results of the performance testing described above demonstrate that the Sage-2 in-1 Personal Lubricant and Moisturizer is as safe and effective as the predicate device and supports a determination of substantial equivalence.