



December 19, 2025

Unipack LLC.
Dinesh Patel
President
111 Coolidge street
South Plainfield, New Jersey 07080

Re: K251011
Trade/Device Name: Chiavaye Personal Moisturizer
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 25, 2025
Received: November 25, 2025

Dear Dinesh Patel:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

Indications for Use

510(k) Number (if known)
K251011

Device Name
Chiavaye Personal Moisturizer

Indications for Use (Describe)

Chiavaye personal moisturizer is a 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. Chiavaye personal moisturizer is not compatible with natural rubber latex, polyurethane, or polyisoprene 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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
K251011
Chiavaye Personal Moisturizer

1. Submitter Information

Applicant: Unipack LLC.
Contact: Dinesh L Patel
Address: 3249 Old Frankstown Road, Pittsburgh, Pennsylvania 15239
Phone: (724) 733-7381
Email: Regulatory.affairs@neilmed.com

2. Date prepared: December 18, 2025

3. Subject Device Information

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

4. Predicate Device Information

Device Name: AH! YES OB COCO Personal Lubricant
510(k) Number: K191411
Manufacturer: Bio-Tech Lubricants Limited

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

5. Device Description

Chiavaye Personal Moisturizer is a clear to slightly yellow and odorless oil-based personal lubricant that is not compatible with condoms made of natural rubber latex, polyisoprene, or polyurethane. This device is a non-sterile 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 device is sold as an over-the-counter (OTC) product in 30 mL and 100 mL sizes provided in black 'MIRON' glass, with a Polypropylene (PP) protective cap. The pump cap is made of Polypropylene (actuator), Nitrile (seal), and Polyethylene (tube).

The device is composed of Almond Oil, Coconut Oil, Grape Seed Oil, Sunflower Oil, Evening Primrose Oil, and Vitamin E.

Device specifications for the Chiavaye Personal Moisturizer are listed in Table 1 below.

Table 1: Device Specifications for Chiavaye Personal Moisturizer

Property	Specification
Appearance	Semi-viscous liquid

Color	Clear to slightly yellow
Odor	Odorless
Viscosity (per USP<912>) at 25°C	200-800 cps
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

6. Indications for Use

Chiavaye personal moisturizer is a 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. Chiavaye personal moisturizer is not compatible with natural rubber latex, polyurethane, or polyisoprene condoms.

7. 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

	Water Solubility Human Body Lubricant K251011 Subject Device	AH!YES OB COCO Personal Lubricant K191411 Predicate Device
Indications for Use	Chiavaye personal moisturizer is a 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. Chiavaye personal moisturizer is not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	AH!YES® OB COCO: 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. AH! YES® OB COCO is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.
Base type	Oil	Oil
Primary ingredients	Almond Oil, Coconut Oil, Grape Seed Oil, Sunflower Oil, Evening Primrose Oil, Vitamin E	Sunflower seed oil, Coconut oil, Jojoba seed oil, Dermofeel Viscolid, Grapeseed Oil, Vitamin E
Rx/OTC	OTC	OTC

Water soluble	No	No
Contains water	No	No
Sterile	No	No
Appearance	Smooth, oily, slippery texture	Opaque paste below melt point, oily pale yellow liquid above melt point
Color	Clear to slightly yellow oil	Pale yellow
Odor	Odorless	Slight odor, strengthening with age
Viscosity per USP <912>	200 – 800 cps	Not specified
Total Aerobic Microbial count (TAMC) per USP <61>	<100 cfu/g	<100 cfu/g
Total Yeast and Mold Count (TYMC) per USP <61>	<10 cfu/g	<10 cfu/g
Absence of Pathogenic Organisms per USP <62>	Yes	Yes
Condom Compatibility	Not compatible with natural rubber latex, polyisoprene, or polyurethane condoms	Not compatible with natural rubber latex, polyisoprene, or polyurethane condoms
Biocompatibility Tested	Yes	Yes

The subject and predicate device have similar indications for use and the same intended use – to provide lubrication for intimate sexual activity. The subject and predicate device have different technological characteristics, including different formulations, and specifications for appearance and odor. 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 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.”* The following testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Vaginal Irritation (ISO 10993-23:2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing demonstrate that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and not acutely, systemically toxic.

Shelf-Life

The subject device has a shelf-life of 24 months. Results from accelerated and real-time age testing demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

The compatibility of Chiavaye personal moisturizer with condoms was evaluated in accordance with ASTM D7661-2023 “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.” The results of this test showed Chiavaye personal moisturizer is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that Chiavaye personal moisturizer is as safe and effective as the predicate device and supports a determination of substantial equivalence.