May 9, 2025

Dongguan Yanxuan Biotechnology Co., Ltd.
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, 518000
CHINA

Re: K243107
Trade/Device Name: Water Solubility Human Body Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Received: April 7, 2025

Dear Joyce Yang:

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243107

Device Name
Water Solubility Human Body Lubricant

Indications for Use *(Describe)*
Water Solubility Human Body Lubricant is a personal lubricant for penile, anal 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. 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
K243107
Water Solubility Human Body Lubricant

1. **Submitter Information**

Applicant: Dongguan Yanxuan Biotechnology Co., Ltd.
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2. **Correspondent Information**

Applicant: Shenzhen Joyantech Consulting Co., Ltd.
Contact: Ms. Joyce Yang
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Phone: +86-755-8606919
Email: joyce@cefda.com

3. **Date prepared:** May 5, 2025

4. **Subject Device Information**

Device Trade Name: Water Solubility Human Body Lubricant
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: Agape Warming Personal Lubricant
510(k) Number: K200208
Manufacturer: CC Wellness LLC

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

6. **Device Description**

Water Solubility Human Body Lubricant is a clear, colorless, odorless and semi-viscous personal lubricant that is compatible with condoms made of natural rubber latex and polyisoprene, and is not compatible with polyurethane condoms. This device is a non-sterile personal lubricant for penile, anal, 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 sold as an over-the-counter (OTC) product in 120 mL size provided in clear polyethylene terephthalate (PET) bottle. The bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

The device is composed of Hyaluronic acid, Lubrajel CG, Lubrajel oil, Panthenol, Trimethyl glycine, Pentanediol, Hydroxyacetophenone, Ethylene glycol, Glycerol, Purified water.

Device specifications for the Water Solubility Human Body Lubricant are listed in Table 1 below.

Table 1: Device Specifications for Water Solubility Human Body Lubricant

Property	**Specification**
Appearance	Semi-viscous liquid
Color	Clear
Odor	Odorless
Viscosity (per USP<911>)	3500 – 4500 cps
pH (per USP<791>)	5.6-6.4
Specific gravity (per USP<831>)	0.950-1.100
Osmolality (per USP<785>)	100-150 mOsm/kg (1:5 dilution)
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**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Escherichia coli	Absent
Antimicrobial Effectiveness Testing (per USP <51>)	**Specification**
Bacteria	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
Yeast and Molds	No increase from the initial calculated count at 14 and 28 days

7. Indications for Use

Water Solubility Human Body Lubricant is a personal lubricant for penile, anal 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. 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

	Water Solubility Human Body Lubricant K243107 Subject Device	**Agape Warming Personal Lubricant K200208 Predicate Device**

Indications for Use	Water Solubility Human Body Lubricant is a personal lubricant for penile, anal 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. This product is not compatible with polyurethane condoms.	Agape Warming Personal Lubricant is a personal lubricant for penile, anal 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.
Base type	Water	Water
Primary ingredients	Purified water, Hyaluronic acid, Lubrajel CG, Lubrajel oil, Panthenol, Trimethyl glycine, Pentanediol, Hydroxyacetophenone, Ethylene glycol, Glycerol	water, Propanediol, Gluconolactone, Hydroxyethylcellulose, Sodium Benzoate, Polysorbate 20, Citric Acid and Capsicum Oleoresin
Rx/OTC	OTC	OTC
Sterile	No	No
Appearance	Semi-viscous liquid	Semi-viscous liquid
Odor	Odorless	Odorless
Viscosity per USP <911>	3500 – 4500 cps	2150 – 4000 cps
pH per USP <791>	5.6 – 6.4	3.4 – 4.5
Osmolality per USP <785>	100 – 150 mOsm/Kg (1:5 dilution)	575 – 750 mOsm/kg
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
Antimicrobial Effectiveness Tested per USP <51>	Yes	Yes
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms	Compatible with natural rubber latex and polyisoprene 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 viscosity, pH, and osmolality. 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 3 years. Results from accelerated 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 Water Solubility Human Body Lubricant 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 Water Solubility Human Body Lubricant is compatible with natural rubber latex and polyisoprene condoms. Results showed Water Solubility Human Body Lubricant is not compatible with polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that Water Solubility Human Body Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.