August 16, 2024

Jiangxi Wulinxiang Biological Technology Co., Ltd.
Yang Qi
GM
1F,Building 1,Nanchang LED Industry Innovation Demonstration Park, No. 1111 Changdong Avenue,
Qingshan, Nanchang, Jiangxi 330012
CHN

Re: K240081
Trade/Device Name: WLX & Bio Human Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 11, 2024
Received: July 15, 2024

Dear Yang Qi:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240081

Device Name
WLX & Bio Human Lubricant

Indications for Use *(Describe)*
WLX & Bio Human Lubricant is a water based personal lubricant, 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. This product is not compatible with natural rubber latex, polyurethane, and 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.

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510(k) Summary – K240081
WLX & Bio Human Lubricant

I. General Information on Submitter

Applicant:	Jiangxi Wulinxiang Biological
Address:	1F,Building 1,Nanchang LED Industry Innovation Demonstration Park, No. 1111 Changdong Avenue, Qingshan, Nanchang, Jiangxi 330012 CHN
Telephone:	86 (791) 881-10717
Contact Person:	Yang Qi,
Contact Title:	GM
Email:	13755676363@163.com
Date Prepared:	August 15, 2024

II. General Information on Device

Trade Name:	WLX & Bio Human Lubricant
Common Name:	Personal Lubricant
Regulation Name:	Condom
Regulation Number	21 CFR 884.5300
Device Class:	II
Product Code:	NUC (Lubricant, Personal)

III. Predicate Device

Predicate Device	510(k) Number
pjur@ AQUA Baseline	K200731

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

IV. Description of Device

WLX & Bio Human Lubricant is a non-sterile, water-based, clear gel personal lubricant. It is a Class II medical device classified under 21 CFR 884.5300 (condom) and product code NUC (lubricant, personal). It contains Water, Glycerin, Propylene Glycol, Carbomer, Hydroxyethylcellulose, Triethanolamine, and Phenoxyethanol. The lubricant is not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

The lubricant is packaged in polyethylene (PE) bottles of 100 mL capacity (Model - WLX100).

The specifications for WLX & Bio Human Lubricant are described in **Table 1**.

Table 1. Device Specifications

Parameter	Test Method	Specification
Appearance/Color	Visual	Clear gel
Odor	Olfactory	Odorless
pH	USP<791>	5.5-7.5
Viscosity	USP<912>	100-300 (cps at 25℃)
Osmolality	USP<785>	750-950 mOsm/kg
Antimicrobial Effectiveness	USP <51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2, bacteria should show not be less than 2.0 log reduction at 14 days and no increase from 14-day Count at the 28 day count. Yeasts and molds should show no increase from the initial calculated count at 14 and 28 days.
Total Aerobic Microbial Count (TAMC)	USP<61>	Less than 100 cfu/mL
Total Yeast and Mold Count (TYMC)	USP<61>	Less than 10 cfu/mL
Absence of Pathogenic Organisms (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	USP<62>	Absent

V. Indications for Use

WLX & Bio Human Lubricant is a water based personal lubricant, 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. This product is not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

VI. Substantial Equivalence Discussion

The following table compares the intended use and technological characteristics of the subject and predicate device:

Characteristic / Feature	WLX & Bio Human Lubricant (subject device)	pjur@ AQUA Baseline (predicate device) – K200731	Comparison
Indications for use	WLX & Bio Human Lubricant is a water based personal lubricant, 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. This product is not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Pjur@ AQUA Baseline for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.	Similar: The subject and predicate devices have similar indications for use, and they have the same intended use.
Water-Based Lubricant	Yes	Yes	Same
Over the Counter	Yes	Yes	Same
Not a contraceptive or Spermicide	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Primary Ingredients	Water, Glycerin, Propylene Glycol, Carbomer, Hydroxyethylcellulose, Triethanolamine, and Phenoxyethanol	water, glycerin, ethoxydiglycol, phenoxyethanol, hydroxypropyl guar hydroxypropyltrimonium chloride, hydroxyethylcellulose, and citric acid	Different
Microbial Limits	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <100 cfu/mL Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)* Antimicrobial effectiveness for Category 2, bacteria: not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28 day count. Yeasts and molds: no increase from the initial calculated count at 14 and 28 days.	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <100 cfu/mL Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus*) Antimicrobial effectiveness for Category 2, bacteria: not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28 day count. Yeasts and molds: no increase from the initial calculated count at 14 and 28 days.	Same
Viscosity	100-300 cps at 25^0C	750-1250	Different

Osmolality	750-950 mOsm/kg	500-625 mOsm/kg (diluted 1:3.9)	Different
pH	5.5-7.5	4.1-4.7	Different
Condom Compatibility	Not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Same

The subject and predicate devices have similar indications for use and have the same intended use – to provide lubrication during intimate sexual activity. The subject and predicate devices have different technological characteristics, including different formulations and device specifications. The different technological characteristics do not raise different questions of safety and effectiveness.

VII. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing on the subject lubricant 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"* and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009/(R)2014)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2021)
- Vaginal Irritation (ISO 10993-23: 2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

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

Shelf Life

The subject device is a non-sterile personal lubricant packaged in PE bottles of 100 mL capacity with a 6-month shelf-life in accordance with the results of real time and an accelerated aging study per ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*. The device specifications listed in **Table 1** were tested across the device shelf-life and the subject device met the specifications at all time points.

Condom Compatibility

Condom compatibility testing was not conducted for the subject device. The subject

device is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

VIII. Conclusion

The results of the testing described above demonstrate that WLX & Bio Human Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.