December 23, 2020

Boya Biotechnology Co., Ltd.
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518100
CHINA

Re: K203257
Trade/Device Name: LUBi Water Based Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 10, 2020
Received: November 4, 2020

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 (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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203257

Device Name
LUBi Water Based Personal Lubricant

Indications for Use *(Describe)*
LUBi Water Based Personal Lubricant 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 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

Date Prepared: December 22, 2020

1. Submission Sponsor

Applicant Name	Boya Biotechnology Co., Ltd.
Address	Floor 3, #7, Changfu Rd., Ludong Community, Humen Town, Dongguan, China (523935)
Contact person	Jason Lau
Phone	+86-769-82881368

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, China
Post Code	518000
Phone	+86-755-86069197
Contact person	Joyce Yang
Email	joyce@cefda.com

3. Devices Identification

Trade Name:	LUBi Water Based Personal Lubricant
Common name:	Personal Lubricant
Regulation Number:	884.5300
Regulation Name:	Condom
Regulatory Class:	II
Product Code:	NUC (lubricant, personal)

4. Legally Marketed Predicate Device

Trade Name	Agape Warming Personal Lubricant
Manufacturer	CC Wellness LLC
510(k) Number	K200208
Common name:	Personal Lubricant
Regulation Number	884.5300
Regulation Name	Condom
Regulatory Class	II
Product Code	NUC (lubricant, personal)

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

5. Device Description

LUBi Water Based Personal Lubricant is a clear, colorless, moderate sweet perfume and viscous personal lubricant that is compatible with condoms made of natural rubber latex and polyisoprene. This product is not compatible with polyurethane condoms. 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 product is sold as an over-the-counter (OTC) product in an 8.54 fl. oz. / 250 mL size. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

The device is composed of water (aqua), glycerin, propylene glycol, hydroxyethyl cellulose, sodium hyaluronate, potassium sorbate, citric acid, disodium ethylenediaminetetraacetic acid (EDTA).

The device specifications are listed in Table 1 below:

Table 1 - Device Specifications for LUBi Water Based Personal Lubricant (Subject Device)

Property	Specification
Appearance	Highly viscous liquid
Color	Clear
Odor	Moderate sweet perfume
Viscosity per USP<911>	28,500-30,000 mPa.s
pH per USP <791>	7.5-8.0
Osmolality per USP<785>	1,000-1,100 mOsm/kg
Antimicrobial effectiveness per USP<51>	
Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus,	No less than a 2.0 log reduction from initial count at 14 days and no increase from the 14 day count at 28 days
Candida albicans, Aspergillus niger	No increase from the initial calculated count at 14 and 28 days
Total aerobic microbial count (TAMC) per USP<61> and <1111>	＜100 CFU/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	＜10 CFU/g
Absence of Pathogenic Organisms per USP<62>	
Staphylococcus aureus	Absent

Property	Specification
Salmonella spp.	Absent
Escherichia coli	Absent
Pseudomonas aeruginosa	Absent
Clostridia	Absent
Candida albicans	Absent

6. Intended Use/ Indications for Use

LUBi Water Based Personal Lubricant 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 natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

7. Comparison of technological characteristics

A comparison of the technological features of the subject and predicate devices is provided in **Table 2** below:

Table 2 – Technological Characteristics of Subject Device Compared to Predicate Device

Comparison item	K203257 Subject Device	K200208 Predicate Device
Device Name	LUBi Water Based Personal Lubricant	Agape Warming Personal Lubricant
Indications for Use	LUBi Water Based Personal Lubricant 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 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 lubricant 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.
Water-based	Yes	Yes
Primary ingredients	Water (Aqua), Glycerin, Propylene Glycol, Hydroxyethyl Cellulose, Sodium Hyaluronate, Potassium Sorbate, Citric Acid, Disodium EDTA	Water (Aqua), Propanediol, Gluconolactone, Hydroxyethylcellulose, Sodium Benzoate, Polysorbate 20, Citric Acid and Capsicum Oleoresin
Sterile	No	No

Comparison item	K203257 Subject Device	K200208 Predicate Device
Condom Compatibility	Natural Rubber Latex Polyisoprene	Natural Rubber Latex Polyisoprene
Antimicrobial Tested	Yes	Yes
Biocompatibility Tested	Yes	Yes
Shelf-life	3 years	3 years
OTC use	Yes	Yes

The subject and predicate device do not have identical indications for use statements. The subject device does not include anal use. This change does not represent a new intended use as the intended use of the device is the same as the predicate device, i.e., lubrication during intimate sexual activity. The subject and predicate device have different technological characteristics, including their formulation. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

8. Summary of Performance Data

*Biocompatibility

The biocompatibility evaluations were conducted in accordance with the 2020 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 10993-10:2010)
* Vaginal Irritation (ISO 10993-10:2010)
* Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrated that the subject lubricant is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

*Shelf Life

The subject device is a non-sterile personal lubricant with a 3 years shelf life in accordance with the results of real time aging studies. All device specifications listed in **Table 1** were tested and met the device specifications across the shelf life duration.

*Condom Compatibility

The compatibility of the subject device with condoms was evaluated in accordance with ASTM D7661-10 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results of this test indicated that the subject device

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

9. Conclusions

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