March 28, 2023

R&R Medical Corporation Ltd.
% Kao Chih Hao
Vice President
Voler Biotech Consulting CO., Ltd.
No. 3-1, Lane 58, Hejiang St., Zhongshan Disy.
Taipei City
Taiwan

Re: K220226
Trade/Device Name: X-Y Lubricating Jelly
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: February 17, 2023
Received: February 21, 2023

Dear Kao Chih Hao:

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,

Michael T. Bailey -S

For
Monica 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)*
K220226

Device Name
X-Y Lubricating Jelly

Indications for Use *(Describe)*
X-Y Lubricating Jelly is a personal lubricant, for vaginal and/or penile 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

K220226
X-Y Lubricating Jelly

510(k) Owner:	R&R Medical Corporation Ltd.
Street Address:	No. 4, Ln. 38, Zhongxing N. St., Sanchong Dist., New Taipei City 24158, Taiwan (R.O.C.)
Contact Person:	Wilson Chang
Contact Email:	wcchang@rr-medical.com
Contact Number:	Tel: +886-2-2697-6618
Summary Preparation Date:	March 24, 2023
Trade Name:	X-Y Lubricating Jelly
Common Name:	Personal Lubricant
Device Classification:	Regulation Name: Condom Regulation Number: 21 CFR 884.5300 Product Code: NUC (lubricant, personal) Device Class: Class II
Predicate Device:	OneTouch™ Lubricant Gel 510(k) Number: K142790 Manufacturer: Thai Nippon Rubber Industry Co., Ltd. Product Code: NUC Device Class: Class II

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

Device Description:

X-Y Lubricating Jelly is a non-sterile, water-based personal lubricant compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms. The lubricant formulation consists of water, glycerin, hydroxyethylcellulose, and methylparaben. X-Y Lubricating Jelly is packaged in 35 g and 100 g polyethylene tubes with a flip-top closure. The tube is then packaged in a carton. X-Y Lubricating Jelly is a personal lubricant for over-the-counter (OTC) use.

The device specifications are listed in the tables below:

Table 1: X-Y Lubricating Jelly Device Specifications

Property	**Specification**
Appearance, color	Clear colorless
Odor	Odorless
pH per USP<791>	6.0-7.0
Osmolality per USP<785>	200-900 mOsm/Kg
Viscosity per <USP 912>	600-900 cPs
Antimicrobial effectiveness per USP <51>	Bacteria: NLT 2.0 log reduction from the initial count at 14 days, and no increase from 14 days 'count at 28 days; Yeasts/Molds: No increase from the initial calculated count at 14 and 28 days.
Total aerobic microbial count (TAMC) per USP<61>	< 100 cfu/g
Total yeast and mold count (TYMC) per method equivalent to USP<61>	< 10 cfu/g
Presence of Pathogens per USP<62>	**Specification**
Bile-tolerant gram-negative bacteria	Absent/g
Pseudomonas aeruginosa	Absent/g
Staphylococcus aureus	Absent/g
Salmonella	Absent/g
Escherichia coli	Absent/g
Clostridia	Absent/g
Candida albicans	Absent/g

Indications for Use Statements:

X-Y Lubricating Jelly is a personal lubricant, for vaginal and/or penile 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.

Comparison of Intended Use and Technological Characteristics to the Predicate Device:

In the table below, the predicate for X-Y Lubricating Jelly is OneTouch Lubricant Gel.

Feature	**X-Y Lubricating Jelly K220226**	**OneTouch Lubricant Gel K142790**	**Comments**
Indications for Use	X-Y Lubricating Jelly is a personal lubricant, for vaginal and/or penile application, intended to moisturize and lubricant, to enhance ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is	OneTouch Lubricant Gel is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricant, to enhance ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is	The indications for use statements for the subject and predicate devices are nearly identical, with the same intended use.

	compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	
Base Type	Water	Water	Same: The subject device and predicate device have the same base type.
Shelf-life	3 years	3 years	Same: The subject device and predicate device have the same shelf-life.
Primary Ingredients	Water, Glycerin, Hydroxyethylcellulose, Methylparaben	Water, Hydroxyethylcellulose, Glycerin, Methylparaben, Propylparaben, Cremophor	Differences in formulations do not raise different questions of safety and effectiveness (S&E).
Over the counter use	Yes	Yes	Same: The subject device and predicate device are for OTC use.
Sterile	No	No	Same: The subject device and predicate device are non-sterile.
Condom compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Same: The subject device and predicate device have the same condom compatibility.
Biocompatibility Tested	Yes	Yes	Same: The subject device and predicate device were tested and shown to be biocompatible.
Antimicrobial Tested	Yes	Unknown	Unknown: Potential differences in methods determining preservative effectiveness do not raise different questions of S&E.
Microbial Tested (Total aerobic microbial count, total yeast and mold count, absence of pathogens)	Yes	Yes	Same: The subject device and predicate device completed this testing.
pH Tested	Yes	Unknown	Unknown: Potential differences in pH do not raise different questions of S&E.
Osmolality Tested	Yes	Unknown	Unknown: Potential differences in osmolality do not raise different questions of S&E.
Viscosity Tested	Yes	Unknown	Unknown: Potential differences in viscosity do not raise different questions of S&E.
Shelf-life	3 years	3 years	Same: The subject

			device and predicate device have the same shelf-life.

As stated in the table, the indications for use for the subject and predicate device are nearly identical. Therefore, the subject and predicate devices have the same intended use.

The subject and predicate devices have different technological characteristics. For example, different formulations. The different technological characteristics identified in the table do not raise different questions of safety and effectiveness.

Summary of Performance Data:

Biocompatibility

Biocompatibility studies, including cytotoxicity, sensitization, vaginal irritation, and acute systemic toxicity testing were performed 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",* as follows:

- 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 biocompatible.

Shelf-Life:

The subject device has a shelf-life of 3 years.

The shelf-life duration for the subject device is based on the results of real-time testing. All specifications listed in Table 1 were met throughout the shelf-life duration.

Condom Compatibility:

The compatibility of the subject device was evaluated in accordance with ASTM D7661-18 "*Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.*" X-Y Lubricating Jelly was determined to be compatible with natural rubber latex and polyisoprene condoms, but not polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that X-Y Lubricating Jelly is as safe and effective as the predicate device and support a determination of substantial equivalence.