March 7, 2025

Lelo Inc.
% Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, CO 80127

Re: K243421
Trade/Device Name: Lelo Hex Lubricated Natural Rubber Latex Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: November 2, 2024
Received: January 29, 2025

Dear Kevin Walls:

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

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)*
K243421

Device Name
Lelo Hex Lubricated Natural Rubber Latex Condom

Indications for Use *(Describe)*
The Lelo Hex Lubricated Natural Rubber Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

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.

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510(k) Summary
K243421
Lelo Hex Lubricated Latex Condom

1. **Submitter Information**

Applicant: Lelo Inc.
Address: 5799 Fontanoso Way
San Jose, CA 95138,
Phone: (877) 872-5356

2. **Correspondent Information**

Company: Regulatory Insight
Contact: Kevin Walls
Address: 33 Golden Eagle Lane
Littleton, CO 80127
Phone: (720) 962-5412
Email: kevin@reginsight.com

3. **Date Prepared:** March 7, 2025

4. **Device Information**

Device Name: Lelo Hex Lubricated Natural Rubber Latex Condom
Common Name: Male Natural Rubber Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: HIS (Condom)
Regulatory Class: Class II

5. **Predicate Device Information**

Device Name: One Touch Spiral Condom
510(k) Number: K210294
Sponsor: Thai Nippon Rubber Industry Public Company Limited

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

6. **Device Description**

The Lelo Hex Lubricated Natural Rubber Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

It is a straight walled textured condom with a nipple end and made of natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. It has a nominal length of 190 ± 10 mm, nominal width of 54 ± 2 mm and nominal thickness of 0.06 ± 0.01 mm.

Lelo Hex Lubricated Natural Rubber Latex Condom is packaged in individually sealed flexible laminate foils which is then packaged into an outer consumer cardboard carton. The Lelo Hex Lubricated Natural Rubber Latex Condom is intended for over-the-counter (OTC) use. These condoms conform with FDA-recognized standards ASTM D3492-16 and ISO 4074:2015.

7. Indications for Use Statement

The Lelo Hex Lubricated Natural Rubber Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	Subject Device	**Predicate Device**
Device & Predicate Device	Lelo Hex Lubricated Latex Condom	One Touch Spiral Condom
510(K) Number	K240679	K210294
Product Code	HIS	HIS
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Regulation Name	Condom	Condom
Indications for Use	The Lelo Hex Lubricated Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	The One Touch Spiral Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).
Prescription or Over-The-Counter Use	Over-The-Counter	Over-The-Counter
Condom Material	Natural Rubber Latex	Natural Rubber Latex
Nominal Width	54 ± 2 mm	52 ± 2mm 54 ± 2mm
Nominal Length	190 ± 10 mm	190 ± 10 mm
Nominal Thickness	0.060 ± 0.010 mm	0.080 ± 0.010 mm
Lubricant	L Arginine Lubricant	Silicone Oil
Lubricant Quantity	550 ± 150 mg	Not publicly available
Air Burst Pressure	>1.0 kPa	Not publicly available; met the criteria specified in ISO 4074:2015, *Natural latex rubber condoms - Requirements and test methods*
Air Burst Volume	>18.0 L	
Sterilization	Non-sterile	Non-sterile
Shape	Straight walled, nipple end	Straight wall, spiral head with nipple end (Single and double spiral)
Texture	Hexagonal Textured	Smooth
Shelf life	3 years	5 years

The subject and predicate device have identical indications for use statements, with the exception of device name, and the same intended use – for contraception and for prophylactic purposes. The technological characteristics of the subject device and predicate device are similar in that they are natural rubber latex-based and lubricated. The subject and predicate device have different technological characteristics, including different dimensions, **shelf-life**, **lubricant** formulation, and texture**.** These differences **do not raise** different **questions of safety and effectiveness.**

9. Summary of Non-Clinical Performance Testing

Biocompatibility:

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation, Cytotoxicity, and Sensitization testing, were 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)
- Sensitization (ISO 10993-10:2021)
- Vaginal Irritation (ISO 10993-10:2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The result of testing demonstrates that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and non-acutely, systemically toxic.

Physical Performance Testing:

The Lelo Hex Lubricated Natural Rubber Latex Condom was tested and met all the requirements of ISO 4074:2015 " Natural rubber latex male condom – Requirement and test methods" and ASTM D3492-16 "Standard Specification for Rubber Contraceptives (Male Condoms)" for dimensional, tensile strength, force at break, lubricant quantity, visible defects, elongation, air burst volume and air burst pressure requirements.

Shelf Life:

The Lelo Hex Lubricated Natural Rubber Latex Condom has a three-year shelf-life based on the results of accelerated stability evaluation conducted as required in 21 CFR 801.435. All samples met predefined acceptance criteria.

10. Conclusion

The results of the performance testing described above demonstrate that the Lelo Hex Lubricated Natural Rubber Latex Condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.