November 6, 2020

RB Health (US) LLC
Kyle Prince
Regulatory Specialist
399 Interpace Parkway
Parsippany, NJ 07054

Re: K200672
Trade/Device Name: Durex Penck Standard; Durex Penck XL
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: October 9, 2020
Received: October 9, 2020

Dear Kyle Prince:

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)*
K200672

Device Name
Durex Penck Standard; Durex Penck XL

Indications for Use *(Describe)*
The Durex Penck Standard Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs).

The Durex Penck XL Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs).

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 – K200672

1. Submitter Information

Applicant: RB Health (US) LLC
Address: 399 Interpace Parkway
Parsippany NJ 07054-0224
Phone: 973-404-2715

2. Correspondent Information

Contact: Kyle Prince
Regulatory Specialist
RB Health (US) LLC
Phone: 973-404-2715
Email: kyle.prince@rb.com

3. Date prepared: November 4, 2020

4. Device Information

Device Name:	Durex Penck Standard; Durex Penck XL
Common Name:	Male Natural Rubber Latex Condom
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Regulatory Class:	Class II
Product Code:	HIS (Condom)

5. Predicate Device Information

Device Name:	Lifestyles Zero Lubricated Latex Male Condom
510(k) Number:	K163107
Manufacturer:	Ansell Healthcare Products, LLC
Regulatory Class:	Class II
Product Code:	HIS (Condom)

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

6. Device Description

Durex Penck Standard and Durex Penck XL are natural rubber latex condoms that completely cover the penis with a closely fitted membrane. They are intended to be used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs). These are straight-walled, parallel sided, teat ended, smooth, and non-colored condoms with a silicone-based lubricant. Durex Penck Standard has a nominal length of 190 mm and width of 54 mm with a thickness of 48 microns. Durex Penck XL has a nominal length of 190 mm and width of 57 mm with a thickness of 50 microns. Durex Penck Standard and Durex Penck XL will be packaged in individually sealed flexible laminate foils made of

polyethylene terephthalate, polyethylene, and aluminum. The foils will come packaged in an outer consumer cardboard carton. Durex Penck Standard and Durex Penck XL condoms are 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

The Durex Penck Standard Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs).

The Durex Penck XL Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs).

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

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

Table 1: Indications for Use and Technological Characteristics of the Subject Devices Compared to Predicate

	Predicate Device	**Subject Devices**	**Comparison**
Trade Name	Lifestyles ZERO Lubricated Latex Male Condom	Durex Penck Standard & Durex Penck XL	Not applicable
510(k) number	K163107	K200672	Not applicable
Submitter	Ansell Healthcare Products LLC	RB Health (US) LLC	Not applicable
Product Code	HIS	HIS	Same
Regulation Number	21 CFR 884.5300	21 CFR 884.5300	Same
Regulation Name	Condom	Condom	Same
Indications for Use	The Lifestyles ZERO Lubricated Latex Male Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs)	The Durex Penck Standard Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs). The Durex Penck XL Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs).	Same
Prescription or Over-The- Counter-Use	Over-The-Counter-Use	Over-The-Counter-Use	Same
Materials	Natural Rubber Latex	Natural Rubber Latex	Same

Lubricant Coating	Silicone	Silicone	Same
Lubricant Quantity	400-600 mg	Durex Penck Standard: 400 ± 50 mg Durex Penck XL: 480 ± 50 mg	Similar
Form	Straight wall, nipple ended condom	Straight walled, parallel sided, teat ended, smooth condom	Similar
Use (single or multiple use)	Single use	Single Use	Same
Length	180 ± 10 mm	Durex Penck Standard:190 ± 10 mm Durex Penck XL:190 ± 10 mm	Different
Width	52 ± 2 mm	Durex Penck Standard: 54 ± 2 mm Durex Penck XL: 57 ± 2mm	Different
Thickness	0.045 +/- 0.005 mm	Durex Penck Standard:0.048 + 0.004 / - 0.002 mm Durex Penck XL:0.050 + 0.004 / - 0.002 mm	Different
Air Burst Pressure	Minimum 1 kPa	Burst Pressure ≥ 1.0 kPa	Same
Air Burst Volume	Minimum 18 L	Durex Penck Standard: Burst Volume ≥ 18.0 L Durex Penck XL: Burst Volume ≥ 22.0 L	Different
Sterilization	Non-sterile	Non-sterile	Same
Shelf Life	5 years	5 years	Same

The subject and predicate device have similar indications for use and have the same intended use. The technological characteristics of the subject devices and predicate are similar in that they are natural rubber latex-based, are lubricated with silicone oil, and have the same shelf-life duration. The subject and predicate devices do have different technological characteristics, including different dimensions and specifications (e.g., burst volume). However, the different technological characteristics of the subject devices do not raise different types of safety and effectiveness questions.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization 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"* and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009/R 2014)
- Sensitization (ISO 10993-10:2010/R 2014)
- Vaginal Irritation (ISO 10993-10:2010/R 2014)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrated that the subject devices are biocompatible.

Physical Testing

The Durex Penck Standard and Durex Penck XL were tested and met all the requirements of ISO 4074:2015 - Natural rubber latex male condoms – Requirements and test methods and ASTM D3492-16 - Standard Specification for Rubber Contraceptives (Male Condoms).

Shelf-Life

The Durex Penck Standard and Durex Penck XL have a five-year shelf life based on the results of accelerated stability evaluations 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 Durex Penck Standard and Durex Penck XL are as safe and effective as the predicate device and supports a determination of substantial equivalence.