October 12, 2022

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

Re: K222068
Trade/Device Name: Durex Penck III Regular
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: July 13, 2022
Received: July 14, 2022

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,

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)*
K222068

Device Name
Durex Penck III Regular

Indications for Use *(Describe)*
The Durex Penck III Regular 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K222068
Durex Penck III Regular

1. Submitter Information

Applicant: RB Health (US) LLC
Address: 399 Interpace Parkway Parsippany
NJ 07054-0024
Phone: (862) 325-0012

2. Correspondent Information

Company: RB Health (US) LLC
Contact: Kyle Prince
Phone: (862) 325-0012
Email: kyle.prince@reckitt.com

3. Date prepared: October 7, 2022

4. Device Information

Device Name:	Durex Penck III Regular
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:	Durex Penck Standard, Durex Penck XL
510(k) Number:	K200672
Sponsor:	RB Health (US) LLC
Manufacturer:	Reckitt Benckiser LLC

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

6. Device Description

Durex Penck III Regular are natural rubber latex-based condoms that completely cover the penis with a closely fitted membrane. Durex Penck III Regular are made of a non-colored natural rubber latex with silicone lubricant and are taper shaft, teat ended smooth shaped condoms. Durex Penck III Regular have a nominal length of 195 mm, width of 56 mm, and thickness of 48 µm and are provided in Regular and Extra Lubricant varieties with 400 mg and 480 mg silicone lubricant respectively. The condoms are packaged in individually sealed flexible laminate foils made of polyethylene terephthalate, polyethylene, and aluminum. The foils are packaged in an outer consumer cardboard carton. The number of condoms in the carton may vary. Durex Penck III Regular condoms are intended for over-the-counter (OTC) use. These condoms conform with FDA-recognized standards ASTM D3492-16 and ISO 4074:2015.

Device specifications are listed in Table 1 below.

7. Indications for Use Statement

The Durex Penck III Regular 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 intended use and technological characteristics of the subject and predicate devices.

Table 1. Comparison of Intended Use and Technological Characteristics

	Subject Device **Durex Penck III Regular** **K222068**	**Predicate Device** **Durex Penck Standard,** **Durex Penck XL** **K200672**
Device & Predicate Device	Durex Penck III Regular	Durex Penck Standard Durex Penck XL
510(K) Number	K222068	K200672
Product Code	HIS	HIS
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Regulation Name	Condom	Condom
Indications for Use	The Durex Penck III Regular 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).
Prescription or Over-The-Counter Use	Over-The-Counter	Over-The-Counter
Condom Material	Natural Rubber Latex	Natural Rubber Latex
Width	Nominal: 56 ± 2 mm Mid Body: 54 ± 2 mm	Durex Penck Standard: 54 ± 2 mm Durex Penck XL: 57 ± 2 mm
Nominal Length	195 ± 10 mm	190 ± 10 mm
Nominal Thickness	0.048 ± 0.008 mm	Durex Penck Standard: 0.048 +0.004 /

		- 0.002 mm Durex Penck XL:0.050 + 0.004 / - 0.002 mm
Lubricant	Silicone	Silicone
Lubricant Quantity	Durex Penck III Regular: 400 ± 50 mg Durex Penck III Regular Extra Lubricant: 480 ± 50 mg	Durex Penck Standard: 400 ± 50 mg Durex Penck XL: 480 ± 50 mg
Air Burst Pressure	> 1.0 kPa	> 1.0 kPa
Air Burst Volume	18.0 L	Durex Penck Standard: Minimum 18.0 L Durex Penck XL: Minimum 22.0 L
Sterilization	Non-Sterile	Non-sterile
Texture	Taper shaft, teat ended smooth condom	Smooth, straight walled, and teat ended
Shelf Life	5 Years	5 Years
Color Additives	N/A	N/A
Flavor Additives	N/A	N/A

The subject and predicate device have similar indications for use and have the same intended use. The technological characteristics of the subject device and predicate device are similar in that they are natural rubber latex-based, are lubricated with silicone, 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 questions of safety and effectiveness.

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 testing demonstrate that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and not acutely, systemically toxic.

Physical Performance Testing:
The Durex Penck III Regular was 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 III Regular has 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 III Regular is as safe and effective as the predicate device and supports a determination of substantial equivalence.