October 27, 2023

Suretex Limited
% Carole C. Carey
Senior Consultant
C3-Carey Consultants, LLC
9451 Ellsworth Court
Fulton, MD 20759

Re: K231908
Trade/Device Name: 45 Micron Polyisoprene Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: September 27, 2023
Received: September 27, 2023

Dear Carole C. Carey:

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.

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

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)*
K231908

Device Name
45 Micron Polyisoprene Condom

Indications for Use *(Describe)*
The 45 Micron Polyisoprene 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.

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510(k) Summary
K231908
45 Micron Polyisoprene Condom

1. Submitter Information

Applicant: Suretex Limited
Address: 31/1 Moo 4, Suratthani-Thakuapha Road
Tambon Khao Hua Kwai, Amphur Phunphin
Suratthani, 84130, THAILAND
Phone: +61 412 119 827

2. Correspondent Information

Company: Global QA RA
Contact: Alison Arnot
Email: Alison.Arnot@lifestyles.com

3. Date prepared: October 25, 2023

4. Device Information

Device Name:	45 Micron Polyisoprene Condom
Common Name:	Polyisoprene Condom
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	MOL (Condom, Synthetic)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	SKYN Original Polyisoprene Lubricated Male Condom
510(k) Number:	K160399
Sponsor:	Ansell Healthcare Products, LLC

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

6. Device Description

The 45 Micron Polyisoprene Condom is a male contraceptive prophylactic device made from synthetic rubber (Polyisoprene latex) with a lubricant coating containing silicone gel with fragrance oil (Sensual Masking). The fragrance oil acts as a masking agent to minimize odor originated from the condom substrate. The condom is a fitted sheath with an integral ring at the open end and a reservoir (nipple end) at the closed end to contain semen. The condom dimensions are length 190 ± 10mm, width 53 ± 2mm, and thickness 0.045 ± 0.005mm. The condom is designed to conform to the requirements of ISO 23409:2011. This product has a 3-year shelf-life. Device specifications are listed in Table 1 below.

7. Indications for Use Statement

The 45 Micron Polyisoprene 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.

	Subject Device 45 Micron Polyisoprene Condom (K231908)	**Predicate Device SKYN Original Polyisoprene Lubricated Male Condom (K160399)**
Device & Predicate Device	45 Micron Polyisoprene Condom	SKYN Original Polyisoprene Lubricated Male Condom
510(K) Number	K231908	K160399
Product Code	MOL	MOL
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Regulation Name	Condom	Condom
Indications for Use	The 45 Micron Polyisoprene 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 Skyn Original Polyisoprene Lubricated 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).
Prescription or Over-The-Counter Use	Over-The-Counter	Over-The-Counter
Condom Material	Polyisoprene	Polyisoprene
Nominal Width	53 ± 2 mm	53 ± 2 mm
Nominal Length	190 ± 10 mm	190 ± 10 mm
Nominal Thickness	0.045 ± 0.005 mm	0.070 ± 0.005 mm
Lubricant	Silicone Oil	Silicone Oil
Sterilization	Non-Sterile	Non-sterile
Shape	Straight-walled & Reservoir-ended	Straight-walled & Reservoir-ended
Texture	Smooth Surface	Smooth Surface
Shelf Life	5 Years	5 Years
Color Additives	N/A	N/A
Flavor Additives	N/A	N/A

The subject and predicate device have identical indications for use statements and the same intended use. The technological characteristics of the subject and predicate devices are similar in that they are polyisoprene-based and are lubricated with silicone oil. The subject and predicate condoms also have identical formulations. There are differences in dimensions and specifications; the subject device has reduced thickness compared to the predicate device. 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 Testing, Cytotoxicity and Sensitization testing were leveraged from the predicate device submission and 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 subject condom was tested for compliance with ISO 23409:2011, "Male Condoms – Requirements and test methods for condoms made from synthetic materials" and ISO 4074:2015, "Natural rubber latex male condoms – Requirements and test methods" for dimensional, tensile strength, force at break, lubricant quantity, visible defects, elongation, air burst volume and air burst pressure requirements. In addition, condoms were tested for tear resistance according to ASTM D624-00 (2020) ("Standard Test Methods for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers") and the 1995 FDA guidance document "Testing Guidance for Male Condoms Made From New Material (Non-Latex)." The subject condom met the predefined acceptance criteria.

Package Integrity:
An evaluation of seal integrity was performed on three lots (3) of the subject device according to ASTM D6324-11 with satisfactory results.

Barrier Properties/Permeability:
A viral penetration study was performed on three (3) test lots of the subject polyisoprene condom, one lot of the commercially available predicate device, and a natural rubber latex condom comparator per ISO 23409: 2011. The cumulative results of the studies demonstrate the barrier effectiveness of the subject device as compared to the predicate device and natural rubber latex control condom for viral penetration under conditions of the *in vitro* study.

Shelf Life:
The 45 Micron Polyisoprene Condom has a five-year shelf life based on the results of accelerated stability evaluations conducted as required in 21 CFR 801.435 and ASTM D6324-11. All samples met predefined acceptance criteria.

Clinical In-Use Slip/Break:
Clinical testing was performed to support clinical performance of the subject device. The physical performance testing described above demonstrated that the subject device had comparable physical

performance to the predicate device, regarding tensile strength, force at break, tensile elongation, airburst pressure, airburst volume, and tear resistance. The slippage and breakage study followed a protocol prepared to meet the FDA guidance " Testing Guidance for Male Condoms Made From New Material (Non-Latex)" was conducted using a polyurethane condom and a standard natural rubber latex condom as comparators. Over 267 couples were included in the study, the clinical breakage rate for the polyisoprene condom was 1.3% compared to 0.7% for the natural rubber latex control. The clinical slippage rate was 0.6% for the polyisoprene condom and 0.6% for the natural rubber latex control. The total clinical failure rate was 1.9% for the polyisoprene condom compared to 1.3% for the natural rubber latex control. The polyisoprene condom was statistically non-inferior from the natural rubber latex control in clinical breakage, slippage, and total clinical failure rate. The 45 Micron Polyisoprene Condom was non-inferior to the control latex condom in clinical breakage, slippage, and total clinical failure rate.

10. Conclusion

The results of the performance testing described above demonstrate that the 45 Micro Polyisoprene Condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.