October 5, 2023

Suretex Limited
% Donna DiGangi
Principal
DiGangi Consulting, LLC
708 Firethorn Lane
Round Rock, TX 78664

Re: K232279
Trade/Device Name: LifeStyles® NRL Textured Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: July 27, 2023
Received: July 31, 2023

Dear Donna DiGangi:

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 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)*
K232279

Device Name
LifeStyles® NRL Textured Condom

Indications for Use *(Describe)*
The LifeStyles NRL Textured Condom is used for contraception and 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.

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510(k) Summary
K232279

Submitter:

Suretex Limited
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Contact Person:

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Date Prepared:

September 28, 2023

Device Name:

Trade Name:	LifeStyles® NRL Textured Condom
Common Name:	Male natural rubber latex condom
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Device Class:	Class II
Product Code:	HIS (Condom)

Predicate Device Information:

Trade Name:	FAMA Male Latex Condoms
510K Number:	K220576
Manufacturer:	Shanghai Personage Hygiene Products Co. Ltd
Common Name:	Male natural rubber latex condom
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Device Class:	Class II
Product Code:	HIS (Condom)

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

Device Description:

The LifeStyles® NRL Textured Condom is indicated for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections). The condom is a single use device made of a non-colored natural rubber latex sheath that covers the penis with a closely fitted membrane. The condom is textured with dots along its straight shaft, includes a reservoir tip at the closed end to contain semen, and is coated with a silicone lubricant. The LifeStyles® NRL Textured Condom has a nominal length of 190 mm, width of 53 mm, and thickness of 0.08 mm. Each condom is packaged individually in laminate foils that are secondarily packaged in cardboard shelf boxes.

The LifeStyles® NRL Textured Condom conforms with FDA-recognized consensus standards ASTM D3492-16 - *Standard Specification for Rubber Contraceptives (male condoms)* and ISO 4074:2015 - *Natural Rubber Latex Condoms – Requirements and test methods*.

Table 1. Condom Specifications

Parameter	Specification
Lubricant quantity (mg)	400 – 600
Length (mm)	190±10
Width (mm)	53 ± 2
Thickness (mm)	0.080± 0.01
Burst Volume, min (dm^3)	18
Burst Pressure, min (kPa)	1.0

Indications for Use:

The LifeStyles NRL Textured Condom is used for contraception and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Comparison of Intended Use and Technological Characteristics with the Predicate Device

Table 2. Technological Characteristics and Comparison to the Predicate Device

Parameter	Subject Device	Predicate Device	Comparison
Device Name	LifeStyles® NRL Textured Condom K232279	FAMA Male Latex Condoms K220576	
Product Code	HIS	HIS	Same
Class	II	II	Same
Classification	21 CFR 884.5300, Condom	21 CFR 884.5300, Condom	Same
Indications for Use	The LifeStyles NRL Textured Condom is used for contraception and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	The FAMA Male Latex Condoms are used for contraception and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	Same
Prescription or Over the Counter (OTC) Use	OTC	OTC	Same
Style	Straight-walled, nipple ended	Straight-walled, nipple ended	Same
Texture	Dotted	Smooth, ribbed, or dotted texture	**Different**
Color Additives	No	No	Same
Formulation	Natural Rubber Latex	Natural Rubber Latex	Same
Lubricant	Silicone oil	Silicone oil	Same
Dusting Agent	USP Grade Corn Starch	Silicon dioxide	**Different**
Length (mm)	190±10	180±10	**Different**
Width (mm)	53 ± 2	53 ± 2	Same
Thickness (mm)	0.080mm ± 0.01	0.068 – 0.069	**Different**
Burst Volume (dm^3)	≥18	≥18	Same
Burst Pressure(kPa)	≥1.0	≥1.0	Same
Sterile	No	No	Same
Shelf Life	5 years	5 years	Same

The subject device has the same indications for use and intended use as the predicate device. The subject and predicate devices have differences in their technological characteristics (e.g., dusting agent, texture, length and thickness); however, these differences do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance testing

Biocompatibility

Biocompatibility studies 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* summarized below:

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

Physical Property Testing

The LifeStyles® NRL Textured Condom was tested and met the requirements of ASTM D3492-16 *Standard Specification for Rubber Contraceptives (Male Condoms)* and ISO 4074:2015 *Natural Rubber Latex Condoms – Requirements and test methods*.

Shelf-Life

The LifeStyles® NRL Textured Condom 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.

Conclusion

The results of performance testing demonstrate that the LifeStyles® NRL Textured Condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.