November 18, 2025

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

Re: K252521
Trade/Device Name: LifeStyles® HydraFeel Natural Rubber Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: July 31, 2025
Received: August 11, 2025

Dear Digangi Donna:

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 Center for Devices and Radiological Healther (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, the Food and Drug Administration (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)*
K252251

Device Name
Lifestyles® HydraFeel Natural Rubber Latex Condom

Indications for Use *(Describe)*
The Lifestyles® HydraFeel Natural Rubber Latex 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
K252521

Submitter:

Suretex Limited
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Tambon Khao Hua Kwai, Amphur Phunphin
Suratthani 84130 THAILAND

Contact Person:

Nicolas Coltel
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Date Prepared:

November 17, 2025

Device Name:

510K Number:	K252521
Trade Name:	LifeStyles® HydraFeel Natural Rubber Latex Condom
Common Name:	Male Natural Rubber Latex Condom
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Regulatory Class:	Class II
Product Code:	HIS (Condom)

Predicate Device Information:

510K Number:	K163107
Manufacturer:	Suretex, Limited
Trade Name:	LifeStyles Zero Lubricated Latex Condom

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

Device Description:

The LifeStyles® HydraFeel Natural Rubber Latex Condom is a single use condom made of natural rubber latex, featuring a straight-shaft, smooth-walled membrane that closely fits the penis. It acts as an barrier to prevent the transmission of sperm, bodily fluids, or STIs into the reproductive tract. The condom is coated with an aqueous lubricant and includes an integral bead at the open end for retention and a reservoir tip at the closed end to contain semen. The LifeStyles® HydraFeel Natural Rubber Latex Condom has a nominal length of 180 mm, width of 52 mm, and thickness of 0.045 mm. Each condom is packaged individually in laminate foils that are secondarily packaged in cardboard shelf boxes.

The device conforms with all sections of consensus standards ISO 4074:2015, *Natural rubber latex male condoms – Requirements and test methods*, and ASTM D3492-16, *Standard Specification for Rubber Contraceptives (Male Condoms)*.

Table 1. Condom Specifications

Parameter	Specification
Lubricant quantity (mg)	760 ± 15
Length (mm)	180 ± 10
Width (mm)	52 ± 2
Thickness (mm)	0.045 ± 0.005
Burst Volume, min (dm^3)	18
Burst Pressure, min (kPa)	1.0
Freedom from Holes	Pass, AQL 0.25
Visible defects	Pass, AQL 0.4

Indications for Use:

The LifeStyles® HydraFeel Natural Rubber Latex Condom is used for contraception and for prophylactic purposes to help reduce the risk of pregnancy and the transmission of sexually transmitted infections (STIs).

Comparison of Intended Use and Technological Characteristics with the Predicate Device

Table 2. Technological Characteristics and Comparison to the Predicate Device:

Parameter	Device	Predicate	Comparison
Device Name	LifeStyles® HydraFeel Natural Rubber Latex Condom	Lifestyles® Zero Lubricated Male Condom	
510(k) Number	K252521	K163107	
Product Code	HIS	HIS	Same
Class	II	II	Same
Classification	21 CFR 884.5300, Condom	21 CFR 884.5300, Condom	Same
Indications for Use	LifeStyles® HydraFeel Natural Rubber Latex 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 Lifestyles® Zero 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).	Same
Style	Straight-walled, integral bead, nipple end	Straight-walled, integral bead, nipple end	Same
Formulation	Natural Rubber Latex	Natural Rubber Latex	Same
Lubricant	Aqueous	Silicone	Different; does not raise new questions of safety and effectiveness
Dusting Agent	USP Grade Cornstarch	USP Grade Cornstarch	Same
Retention Mechanism	Integral Bead	Integral Bead	Same
Length (mm)	180±10	180±10	Same
Width (mm)	52 ± 2	52 ± 2	Same
Thickness (mm)	0.045 ± 0.005	0.045 ± 0.005	Same
Sterile	No	No	Same
Burst Volume, min (dm^3)	18	18	Same
Burst Pressure, min (kPa)	1.0	1.0	Same
Freedom from Holes	Pass, AQL 0.25	Pass, AQL 0.25	Same
Shelf Life	5 years	5 years	Same

The device has the same indications for use and the same intended use as the predicate device. The subject device and predicate device have differences in their technical characteristics (e.g., latex formulation and lubricant formulation).; however, these differences do not raise different questions of safety or effectiveness.

Summary of Non-Clinical Performance testing

Biocompatibility

Biocompatibility studies 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", 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-sensitizing, non-irritating, and not acutely systemically toxic.

Physical Property Testing

LifeStyles® HydraFeel Natural Rubber Latex 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

LifeStyles® HydraFeel Natural Rubber Latex 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 LifeStyles® HydraFeel Natural Rubber Latex Condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.