April 28, 2022

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

Re: K213921
Trade/Device Name: Microthin Natural Rubber Latex Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 21, 2022
Received: March 28, 2022

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 (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213921

Device Name
Microthin Natural Rubber Latex Condom

Indications for Use *(Describe)*
The Microthin Natural Rubber Latex 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K213921

Submitter:

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Date Prepared:

April 26, 2022

Device Name:

Trade Name:	Microthin Natural Rubber Latex 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:

K192669, Extremely Thin 003, ZERO ZERO THREE (Okamoto U.S.A, Inc.)

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

Device Description:

The Microthin Natural Rubber Latex Condom is a male contraceptive made of natural rubber latex that completely covers the penis with a closely fitted membrane sheath. The condom is provided lubricated with silicone oil. The condom is straight-walled, with a smooth surface and a reservoir (nipple end) at the closed end to contain semen. The condom dimensions are length 170mm ± 10mm, width 52 ± 2mm, and thickness 0.035mm ± 0.005mm. The condom conforms to the recognized standards ASTM D3492-16 *Standard Specification for Rubber Contraceptives (male condoms)* and ISO 4074:2015 *Natural Rubber Latex Condoms – Requirements and test methods.* The condom has a 5-year shelf-life.

Indications for Use:

The Microthin Natural Rubber Latex 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:

The table below compares the intended use and technological characteristics of the subject and predicate devices:

	Subject Device K213921	**Predicate Device K192669**	**Comparison**
Indications for Use	The Microthin Natural Rubber Latex Condom is used for contraception and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	The condom is used for contraception and for prophylactic purposes (preventing transmission of sexually transmitted infections).	The subject and predicate indications for use are not identical, but both have the same intended use (i.e., to prevent pregnancy and transmission of sexually transmitted infections).
Condom Material	Natural Rubber Latex	Natural Rubber Latex	Same

Nominal Width	52 ± 2 mm	53.2 ± 2 mm	Different
Nominal Length	170 ± 10 mm	180 ± 10 mm	Different
Nominal Thickness	0.035 ± 0.005	30 mm from closed end: 0.039 ± 0.0013 90 mm from closed end: 0.039 ± 0.001 150 mm from closed end: 0.039 ± 0.001	Different
Lubricant	Silicone	Silicone	Same
Color Additives	No color	No color	Same
Flavor Additives	No flavor	No flavor	Same
Shape	Straight-walled Reservoir-ended	Straight-walled Reservoir-ended	Same
Texture	Smooth Surface	Smooth Surface	Same
Bursting Pressure (kPa)	Minimum of 1 kPa	1.42 ± 0.10	Different
Bursting Volume (dm^3)	Minimum of 18 L	35.4 ± 3.83	Different
Shelf-life	5 years	5 years	Same

As shown in the table above, the subject and predicate devices do not have identical indications for use statements; however, they do have the same intended use (i.e., to prevent pregnancy and transmission of sexually transmitted infections).

The technological characteristics of the subject and predicate device are similar in that they are natural rubber latex-based, do not contain colorants or flavors, have the same shape and texture, and have the same shelf-life. Differences between the subject and predicate device include dimensions of the condoms (e.g., width, length, and thickness) and burst specifications. These differences in technological characteristics do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing:

The following testing has been performed to support substantial equivalence to the predicate device:

Physical Testing

Three lots of the subject device were tested at baseline and met the airburst specifications 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 Testing

Shelf-life testing was conducted to support a shelf-life of five years per the requirements of 21 CFR §801.435. All samples met the predefined acceptance criteria.

Biocompatibility Testing

Biocompatibility testing was conducted 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." Testing included the following assessments:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute systemic toxicity (ISO 10993-11:2017)

The device was demonstrated to be biocompatible.

Conclusion:

The results of the performance testing described above demonstrate that the Microthin Natural Rubber Latex Condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.