September 7, 2023

TTK Healthcare Limited
Daniel J S
Head - Corporate RA/QA [Medical Devices]
6, Cathedral Road
Chennai, Tamil Nadu 600086
India

Re: K230049
Trade/Device Name: SKORE Male Natural Rubber Latex Condoms
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: August 3, 2023
Received: August 8, 2023

Dear Daniel J S:

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 -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)*
K230049

Device Name
SKORE Male Natural Rubber Latex Condoms

Indications for Use *(Describe)*
SKORE Male Natural Rubber Latex Condoms are used for contraception and for 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 – K230049

TTK Healthcare Ltd.

SKORE Male Natural Rubber Latex Condoms

ADMINISTRATIVE INFORMATION

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Date prepared: September 6, 2023

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	SKORE Male Natural Rubber Latex Condoms
Common Name:	Male Natural Rubber Latex Condom
Regulation Number:	21 CFR 884.5300
Regulation Name	Condom
Regulatory Class:	II
Product Code:	HIS (condom)

PREDICATE DEVICE

K211152: Durex Condom with Benzocaine

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

DEVICE DESCRIPTION

The subject SKORE Male Natural Rubber Latex Condoms are made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane and used

for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted infections. The subject device in this submission consists of

- **SKORE Smooth, Dotted &Thin Condoms**

  SKORE Smooth Condoms -SKORE Blues Vanilla Scented. These condoms are straight walled, smooth, blue colored, teat ended, natural rubber latex having a length of 190 ± 10 mm, width of 53±2mm and a thickness of 0.060 to 0.074 mm, meeting the requirements as specified in ASTM D3492 and ISO 4074. The subject device includes the color blue and flavor vanilla.

  SKORE Dotted Condoms -SKORE Warm Belgian Chocolate & SKORE Dots Vanilla Scented; These condoms are straight walled, raised dots, teat ended, natural rubber latex condoms having a length of 190 ± 10 mm, width of 53 ±2 mm and a thickness of 0.060 to 0.080 mm, meeting the requirements as specified in ASTM D3492 and ISO 4074. The subject device includes the color brown and flavors Belgium chocolate and vanilla.

  SKORE Thin Condoms – SKORE NOTHING Chocolate, SKORE NOTHING Strawberry & SKORE SKINTHIN Ultra fine Condoms. These condoms are straight walled, smooth, thin, teat ended, natural rubber latex condoms having a length of 190 ± 10 mm, width 53±2mm and a thickness of 0.045 to 0.055 mm, meeting the requirements as specified in ASTM D3492 and ISO 4074. The subject device includes the flavors strawberry and chocolate.

- **SKORE Bulbous Condoms**

  SKORE WARM and SKORE COOL Condoms – These condoms are bulbous dotted, ribbed, and colored natural rubber latex condoms having a length of 190 ± 10 mm, width 56±2mm, meeting the requirements as specified in ASTM D3492 and ISO 4074. The subject device includes the colors orange and blue and flavors warming lubricant and cool tropic mint.

- **SKORE Benzocaine Condoms**

  SKORE NOTHING Climax Delay – These condoms are straight walled, thin, teat ended, natural rubber latex condoms having a length of 190 ± 10 mm, width 53 ±2 mm and a thickness of 0.050 to 0.060, mm meeting the requirements as specified in ASTM D3492 and ISO 4074.

SKORE Duo Max - These condoms are bulbous transparent dotted & ribbed, teat ended, natural rubber latex condoms having a length of 190 ± 10 mm, width of 56±2 mm meeting the requirements as specified in ASTM D3492 and ISO 4074.

SKORE NOT OUT - These condoms are straight walled, raised dots, red colored, teat ended, natural rubber latex condoms having a length of 190 ± 10 mm, width of 53 ±2 mm and a thickness of 0.060 to 0.080 mm meeting the requirements as specified in ASTM D3492 and ISO 4074. The subject device includes the color red.

INDICATIONS FOR USE

SKORE Male Natural Rubber Latex Condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

PREDICATE DEVICE COMPARISON

The table below compares the intended use and technological characteristics of the subject and predicate device.

Substantial Equivalence Table:

<table>
<tr><th>Subject Device & Predicate Device</th><th colspan="2">SKORE Male Natural Rubber Latex Condoms</th><th>K211152 (Durex Condoms with Benzocaine)</th></tr>
<tr><td>Indications for Use</td><td colspan="2">SKORE Male Natural Rubber Latex Condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).</td><td>The Durex Condom with Benzocaine is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs)</td></tr>
<tr><td>Dusting Powder</td><td colspan="2">Magnesium Carbonate & Calcium Carbonate</td><td>-</td></tr>
<tr><td>Condom Material</td><td colspan="2">Natural Rubber Latex</td><td>Natural Rubber Latex</td></tr>
<tr><td rowspan="4">Nominal Width</td><td>Thin</td><td>53 ± 2 mm</td><td rowspan="4">56±2 mm</td></tr>
<tr><td>Bulbous</td><td>56 ± 2 mm</td></tr>
<tr><td>Dotted</td><td>53 ± 2 mm</td></tr>
<tr><td>Smooth</td><td>53 ± 2 mm</td></tr>
</table>

Nominal Length	190±10 mm		195±10 mm
Nominal Thickness	Thin	0.045- 0.055 mm	0.065±0.010 mm
	Dotted	0.060 - 0.080 mm	
	Smooth	0.060- 0.074 mm	
	Nothing Climax Delay	0.050-0.060 mm	
	NOT OUT	0.060-0.080 mm	
	DUO MAX	0.075-0.095 mm	
Lubricant	Silicone Oil/ Zeus Odor Masker flavoring, benzocaine cream, or warming.		Silicone gel with Transatak odor masker and benzocaine
Lubricant Quantity	Smooth, dotted, thin , and vanilla condoms	500 ± 50 mg	480 ± 50 mg
	Belgian chocolate, strawberry, chocolate, and skinthin	400 ± 50mg	
	Warm	600 ± 50 mg	
	Cool tropical mint	600 ± 50mg	
	Benzocaine condoms	400 ± 50 mg & 480 ± 50 mg	
Benzocaine Quantity	120- 160 mg (4.75 – 5.25 %) Benzocaine cream / Retardant solution		140 ± 20 mg (4.75 – 5.25 %) Benzocaine
Air Burst Test Pressure	> 1.0 kPa		> 1.0 kPa
Air Burst Test Volume	18 dm^3		18 dm^3
Texture	Smooth, dotted & thin		-
Shelf Life	5 Years		5 Years
Color Additives	Blue, Brown, Orange, Red & Blue		-

Flavor Additives	Vanilla, Belgian Chocolate, Vanilla, Strawberry Chocolate, Warming Lubricant (Orange), & Cool Tropic Mint flavor (Blue)	-
Prescription or Over-The-Counter use	Over- The- Counter	Over- The- Counter
Packaging Material	Laminate consisting of a layer of suitable impermeable flexible aluminum foil, and layers of plastic materials suitable for the mechanical protection of the metal foil and or printing and sealing.	Laminate consisting of a layer of suitable impermeable flexible aluminum foil, and layers of plastic materials suitable for the mechanical protection of the metal foil and or printing and sealing.

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, have the same shelf-life duration, and for the SKORE Benzocaine Condoms, they have the same amount of benzocaine. The subject and predicate devices have different technological characteristics, including different lubricant quantities, dimensions, and specifications. However, the different technological characteristics of the subject devices do not raise different questions of safety and effectiveness.

PERFORMANCE TESTING

Biocompatibility:

Biocompatibility testing was performed on the SKORE Male Natural Rubber Latex Condoms in accordance with ISO 10993-1: Biological Evaluation of Medical Devices.

Test Performed	Standard
Acute Systemic Toxicity Reactivity	ISO 10993-11:2017
In vitro Cytotoxicity	ISO 10993-5:2009
Skin Sensitization	ISO 10993-10:2021
Vaginal Irritation Test	ISO 10993-23:2021

The results of demonstrate that the subject devices are biocompatible.

Mechanical Performance Testing:

Three lots of subject devices, SKORE Male Natural Rubber Latex Condoms were tested at baseline and met specifications of ISO 4074:2015 – Natural rubber latex male condoms – Requirements and test methods and ASTM D3492-16– Standard Specification for Rubber Contraceptives

The results demonstrate that the subject devices meet the standard specifications.

Shelf Life:

Shelf-life testing was conducted per ISO 4074:201521 and 21 CFR 801.435. The accelerated (7 days at 70ºc, 90 days at 40-50ºc) and real-time stability (5 Years at 28º C to 35º C) of the SKORE Male Natural Rubber Latex Condoms supports a shelf-life of five years as per the requirements.

CONCLUSION

The results of the performance testing described above demonstrate that the SKORE Male Natural Rubber Latex Condoms are as safe and effective as the predicate device and supports a determination of substantial equivalence.