April 15, 2021

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

Re: K202403
Trade/Device Name: SKORE (Colors & Flavors), SKORE (Colors)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 15, 2021
Received: March 19, 2021

Dear Daniel 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 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202403

Device Name
SKORE (Colors & Flavors), SKORE (Colors)

Indications for Use *(Describe)*
SKORE Red, SKORE Yellow, SKORE Brown, SKORE Orange & SKORE Strawberry, SKORE Cherry, SKORE Banana, SKORE Pinacolada, SKORE Tangerine, SKORE Chocolate and SKORE Cool Mint, Male Natural Rubber Latex Condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY – K202403

TTK Healthcare Ltd.

SKORE (Colors & Flavors), SKORE (Colors)

Date Prepared: 14th, April 2021

ADMINISTRATIVE INFORMATION

Manufacturer: TTK Healthcare Ltd.
12, K P Natham Road, Thiruvandar Koil,
Puducherry, INDIA 605 102
Telephone: +91 413 2261 401/402

Official Contact: J.S. Daniel
Head - Corporate RA/QA [Medical Devices]
TTK Healthcare Ltd.
No.6, Cathedral Road,
Chennai, Tamilnadu, INDIA – 600 086
Phone: +91 44 4200 8200
Email: daniel.js@ttkhealthcare.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	SKORE (Colors & Flavors), SKORE (Colors)
Common Name:	Male Natural Rubber Latex Condom
Regulation Name:	Condom
Regulation Number	21 CFR 884.5300
Class:	II
Product Code:	HIS (Condom)

PREDICATE DEVICE

Device	Manufacturer	Trade or Proprietary or Model Name	510(k)
Primary Predicate	TTK Healthcare Ltd.	SKORE Natural & Bulbous & |Dots	K132490

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

DEVICE DESCRIPTION

SKORE Condoms (Colors & Flavors) and SKORE Condoms (Flavors) are made of a natural rubber latex sheath and are used for contraception and for prophylactic purposes to

help prevent pregnancy and the transmission of sexually transmitted diseases. The subject devices in this submission consists of

- **SKORE Colors** - SKORE Red; SKORE Yellow; SKORE Brown; SKORE Orange. These condoms are parallel straight walled, teat ended, with a smooth surface Natural Rubber Latex Condoms in the colors Red, Yellow, Brown, and Orange; having a length of 190 ± 10 mm, width of 53±2mm and a thickness of 0.065 ±0.010 mm, per ASTM D3492:2016 and ISO 4074:2015.
- **SKORE Colors & Flavors** - SKORE Strawberry; SKORE Cherry; SKORE Banana; SKORE Pinacolada; SKORE Tangerine; SKORE Chocolate; SKORE Cool Mint. These condoms are parallel straight walled, teat ended, with a dotted surface having a length of 190 ± 10 mm, width of 53 ± 2 mm and a thickness of 0.065 ± 0.010 mm, per ASTM D3492:2016 and ISO 4074:2015.

INDICATIONS FOR USE

SKORE Red, SKORE Yellow, SKORE Brown, SKORE Orange & SKORE Strawberry, SKORE Cherry, SKORE Banana, SKORE Pinacolada, SKORE Tangerine, SKORE Chocolate and SKORE Cool Mint, Male Natural Rubber Latex Condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

SUBSTANTIAL EQUIVALENCE DISCUSSION

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

Device & Predicate Device	K202403 (SKORE (Colors & Flavors) & SKORE (Colors))	K132490 (SKORE Natural, SKORE Dots Natural, SKORE Bulbous Natural and SKORE Bulbous Dots) & Ribs Natural - Male Natural Rubber Latex Condoms.
Indications for Use	SKORE Red, SKORE Yellow, SKORE Brown, SKORE Orange & SKORE Strawberry, SKORE Cherry, SKORE Banana, SKORE Pinacolada, SKORE Tangerine, SKORE Chocolate and SKORE Cool Mint, Male Natural Rubber Latex	SKORE Natural, SKORE Dots Natural, SKORE Bulbous Naturual, SKORE Bulbous Dots & Ribs Natural-Male Natural Rubber Latex Condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of

	Condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).	sexually transmitted diseases)
Dusting Powder	Magnesium Carbonate & Calcium Carbonate	Magnesium Carbonate & Calcium Carbonate
Condom Material	Natural Rubber Latex	Natural Rubber Latex
Nominal Width	53±2	53±2
Nominal Length	190±10 mm	190±10 mm
Nominal Thickness	0.065±0.010mm	0.070±0.010mm
Lubricant	Silicone Oil	Silicone Oil
Air Burst Test Pressure	> 1.0 kPa	> 1.0 kPa
Air Burst Test Volume	18 L	18 dm^3
Texture	Plain & Dotted	Plain & Dotted
Shelf Life	5 Years	5 Years
Color Additives	Red, Yellow, Brown, Orange, Blue	No Colors
Flavor Additives	Strawberry, Cherry, Banana, Pinacolada, Tangerine, Chocolate, Cool Mint	No Flavors
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.

SKORE Condoms (Colors & Flavors) and SKORE Condoms (Colors) and the predicate devices are Male Natural Rubber Latex Condoms and used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases). The subject and the predicate devices have the same intended use. SKORE Condoms (Colors & Flavors) and SKORE Condoms (Colors) and the predicate devices have different technological characteristics, including different colors and flavors used and different dimensions. These differences do not raise different questions of safety and effectiveness.

NON- CLINICAL PERFORMANCE TESTING

The following studies have been performed to support substantial equivalence to the predicate device

Biocompatibility:

Biocompatibility testing was performed on the SKORE Condoms (Colors & Flavors) in accordance with ISO 10993-1: Biological Evaluation of Medical Devices.

Test Performed	Standard
Acute Systemic Toxicity	ISO 10993-11:2006/(R)2010
Cytotoxicity	ISO 10993-5:2009
Vaginal Irritation	ISO 10993-10:2010
Penile Irritation	ISO 10993-10:2010
Skin Sensitization	ISO 10993-10:2010

The results of testing demonstrate that the subject devices are non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Mechanical Performance Testing:
Three lots of the subject devices, SKORE Condoms (Colors & Flavors) and SKORE Condoms (Colors), were tested at baseline and met the specifications of ISO 4074:2015 – *Natural rubber latex male condoms – Requirements and test methods* and ASTM D3492:2016– *Standard Specification for Rubber Contraceptives (Male Condoms).*

Shelf Life:
Shelf life of the SKORE Condoms (Colors & Flavors) and SKORE Condoms (Colors) was established from results of testing data to support a shelf-life of five years per the requirements of 21 CFR 801.435.

CONCLUSION:

The results of the performance testing described above demonstrate that the SKORE Condoms (Colors & Flavors) and SKORE Condoms (Colors) are as safe and effective as the predicate device and support a determination of substantial equivalence.