December 6, 2018

SXWELL USA LLC
Robert Mahler
Director, QA/RA North America and European Union
111 Wood Avenue South
Iselin, New Jersey 08830

Re: K182438
Trade/Device Name: Synthetic Polyisoprene Lubricated Male Condom - 5 Senses
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: MOL
Dated: August 14, 2018
Received: September 7, 2018

Dear Robert Mahler:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K182438

Device Name
Synthetic Polyisoprene Lubricated Male Condom - 5 Senses

Indications for Use *(Describe)*
Synthetic Polyisoprene Lubricated Male Condom - 5 Senses is used for contraception and for prophylactic purposes to help reduce the risk of pregnancy and the transmission of sexually transmitted infections (STI's).

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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510k Summary
K182438

Submitter:

SXWELL USA LLC.
111 Wood Avenue South
Iselin, NJ 08830, USA

Contact Person:

Robert S. Mahler
Director of Quality Assurance & Regulatory Affairs for North America and the European Union
Phone: 732-345-2174
Rob.mahler@lifestyles.com

Date Prepared:
December 4, 2018

Device Name:

Proprietary Name:	Synthetic Polyisoprene Lubricated Male Condom – 5 Senses
Common Name:	Condom, Synthetic
Classification Name:	Condom
Classification Regulation:	21 CFR 884.5300
Device Class:	Class II
Product Code:	MOL (Condom, Synthetic)

Predicate Device:

K171172 – Synthetic Polyisoprene Male Condom - Flavored

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

Device Description:

The Synthetic Polyisoprene Lubricated Male Condom – 5 Senses is a male contraceptive and prophylactic device made from synthetic rubber polyisoprene latex with a lubricant coating containing silicone gel with flavor and sensate. The subject condom is provided in a variety pack which includes three variants; Cooling, Tingling, and Warming.

The condom is a fitted sheath with an integral ring at the open end and a reservoir (nipple end) at the closed end to contain semen. The condom dimensions are length 190±10mm, width 53±2mm, and thickness 0.065-0.075mm. The condom is designed to conform to the requirements of ISO 23409:2011. This product has a 3-year shelf-life.

Indications for Use:

The Synthetic Polyisoprene Lubricated Male Condom – 5 Senses is used for contraception and for prophylactic purposes to help reduce the risk of pregnancy and the transmission of sexually transmitted infections (STI's).

Technological Characteristics:

The comparison of technological characteristics between the Synthetic Polyisoprene Lubricated Male Condom – 5 Senses and the predicate device is shown in the table below:

Device & Predicate Device(s):	**K182438 (subject device)**	**K171172 (predicate device)**	Comparison
Condom Material	Polyisoprene	Polyisoprene	Same
Dimensions	Length 190±10 mm Nominal width 53±2 mm Thickness 0.065-0.075 mm	Length 190±10 mm Nominal width 53±2 mm Thickness 0.065-0.075 mm	Same
Shape	straight wall with a reservoir tip	straight wall with a reservoir tip	Same
Texture	Smooth	Smooth	Same
Lubricant	Silicone oil	Silicone oil	Same
Color Additives	None	None	Same
Fragrance Additives	None	Yes	**Different**
Sensate Additives	Yes	None	**Different**
Dusting Agent	Corn starch	Corn starch (different amount per device)	**Different**

The subject and predicate devices have similar technological characteristics. The primary difference is the use of fragrance and sensate additives in the subject device. These differences in technological characteristics do not raise different questions of safety or effectiveness as compared to the predicate device.

Performance Data:

Performance testing to assess the addition of new fragrant and sensate chemicals to the subject device was conducted in accordance with ISO 23409:2011, "Male Condoms – Requirements and test methods for condoms made from synthetic materials," and the FDA Guidance Document, "Testing guidance for Male Condoms Made from New Material (Non-Latex)." Results of testing showed that the mechanical properties of the subject device were equivalent to the predicate device.

Shelf-life testing was also conducted to demonstrate the subject device met its three-year shelf-life specification. The shelf life testing included an assessment of the mechanical burst properties of the subject device following aging.

In addition, biocompatibility testing was conducted in accordance with ISO 10993-1 to assess the addition of fragrant and sensate additives to the condom lubricant. The following biocompatibility testing was conducted:

- Cytotoxicity (Extraction Method, ISO 10993-5: 2009)
- Sensitization (Guinea Pig Maximization Sensitization, ISO 10993-10:2010)
- Irritation (Dermal, Vaginal, and Penile Irritation Studies in Rabbits, ISO 10993-10:2010)
- Acute Systemic Toxicity (Tests for Systemic Toxicity, ISO 10993-11: 2006)

The remainder of the performance testing outlined in the guidance document was deemed not needed to support the addition of fragrant and sensate chemicals to the condom lubricant.

Conclusion:

The subject and predicate devices have the same intended use and similar fundamental technological characteristics. The performance data demonstrate that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.