DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 25, 2016

Ansell Healthcare Products, LLC.
Robert Mahler
Director, Regulatory Affairs
111 Wood Avenue South, Suite 210
Iselin, NJ 08830

Re: K160399
Trade/Device Name: Skyn Original Polyisoprene Lubricated Male Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: June 21, 2016
Received: June 23, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160399

Device Name
Skyn Original Polyisoprene Lubricated Male Condom

Indications for Use *(Describe)*
The Skyn Original Polyisoprene 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, 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.

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

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510(k) Summary (K160399)

Submitter:

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830, USA

Contact Person:

Robert S. Mahler
Director Regulatory Affairs for the Americas
Phone: 732-345-2174
Rob.mahler@ansell.com

Date Prepared:

July 25, 2016

Device Name:

Proprietary Name:	Skyn Original Polyisoprene Lubricated Male Condom
Common Name:	Condom, Synthetic
Classification Name:	Condom
Classification Regulation:	21 CFR 884.5300
Device Class:	Class II
Product Code:	MOL
Classification Panel:	Obstetrics/Gynecology

Predicate Device:

K070800 - Lifestyles Lubricated Polyisoprene Latex Male Condom

Reason for 510(k) Submission:

The subject device is a modified version of predicate device (K070800). Lubricant coating of subject device contains fragrance oil to improve the aroma and minimize the odor profile of the device for the end user. The fragrance oil has not been utilized previously in the predicate device.

Device Description:

The Skyn Original Polyisoprene Lubricated Male Condom is a male contraceptive and prophylactic device made from synthetic rubber Polyisoprene latex with a lubricant coating containing silicone gel with fragrance oil. Fragrance oil acts as a masking agent to minimize odor originated from condom substrate. 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 ≥180mm, 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 5-year shelf-life.

Indications for Use:

The Skyn Original Polyisoprene 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).

Technological Characteristics:

The technological characteristics of the Skyn Original Polyisoprene Lubricated Male Condom are identical to the predicate device. The only difference is addition of fragrance oil to the lubricant coating of subject device. This difference does not represent a new technology as it does not raise different questions of safety or effectiveness as compared to the predicate device.

Performance Data:

Performance testing conducted to assess the addition of fragrance oil to the condom lubricant followed ISO 23409:2011, "Male Condoms – Requirements and test methods for condoms made from synthetic materials," and 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 demonstrated the device met its five year shelf-life specification. In addition, biocompatibility tests conducted to assess the addition of fragrance oil to the condom lubricant (cytotoxicity, sensitization, irritation, and acute systemic toxicity) had passing results. The remainder of the performance testing outlined in the guidance document was deemed not needed to support the addition of fragrance oil to the condom lubricant.

Conclusion:

The subject and predicate devices have the same intended use and fundamental technological characteristics. The subject device is different from the predicate device in that it contains fragrance oil. However, the difference does not raise new types of questions and can be assessed by biocompatibility testing and performance testing. Performance data demonstrated that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.