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

January 23, 2017

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

Re: K163107
Trade/Device Name: Lifestyles Zero Lubricated Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: HIS
Dated: November 4, 2016
Received: November 7, 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,

Benjamin R. Fisher -S

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)*
K163107

Device Name
Lifestyles Zero Lubricated Latex Male Condom

Indications for Use *(Describe)*
The Lifestyles Zero Lubricated Latex 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).

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 – K163107

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

January 23, 2017

Device Name:

Proprietary Name:	Lifestyles Zero Lubricated Latex Male Condom
Common Name:	Condom, Natural Rubber Latex
Classification Regulation:	21 CFR 884.5300
Device Class:	Class II
Product Code:	HIS; condom
Classification Panel:	Obstetrics/Gynecology
Classification Name:	Condom

Reason for 510(k) Submission:

New product.

Predicate Device:

K941258 – Latex Condom with Silicone Oil Lubricant.
The predicate device has not been subject to a design related recall.

Device Description:

This condom is a single use and non-sterile device intended for in home use by a consumer. The condom is made of a natural rubber latex sheath, which completely covers the penis with closely fitted membrane. The condom provides a physical barrier to fluids which helps reduce the risk of pregnancy and the transmission of sexually-transmitted infections. The device is a straight walled, cylindrical, lubricated condom with a reservoir tip. Condom dimensions are length 180+/- 10 mm, width 52±2mm, and thickness 0.045+/-0.005 mm. The condom is designed to conform to the requirements of ASTM D3492:2015 - Standard Specification for Rubber Contraceptives (Male Condoms).

Indications for Use:
The Lifestyles Zero Lubricated Latex 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 Lifestyles Zero Lubricated Latex Male Condom has the following technological characteristics as compared to ASTM or equivalent standards

Technological Characteristic	**Standard/Test/FDA Guidance**	**Specification**
Dimensions	ASTM D3492-15	
■ Length	170mm to 210 mm	180 +/- 10 mm
■ Width	Maximum 57 mm	52±2 mm
■ Thickness	Minimum 0.03 mm	0.045+/-0.005 mm
Burst Properties	ASTM D3492-15	
■ Air Burst Test Pressure	Minimum 18L	Meets ASTM D3492-15 for Air Burst test pressure
■ Air Burst Test Volume	Minimum 1 kPa	Meets ASTM D3492-15 for Air Burst test volume
Leakage AQL	ASTM D3492-15	Meets ASTM D3492-15 for Leakage AQL of 0.25
Package integrity AQL	ASTM D3492-15	Meets ASTM D3492-15 for Package Integrity AQL of 2.5
Lubricant Quantity	Not defined	400 – 600 mg

Substantial Equivalence:

	Predicate Device	**Subject Device**	**Substantial Equivalence**
Trade Name	Latex Condom with silicone oil lubricant	Lifestyles ZERO	Not applicable
510(k) Number	K941258	K163107	Not applicable
Submitter	Suretex Ltd.	Ansell Healthcare Products LLC	Yes
Product Code	HIS	HIS	Yes
Regulation Number	21 CFR 884.5300	21 CFR 884.5300	Yes
Regulation Name	Condom	Condom	Yes
Indications for Use	This device is a latex condom indicated for contraception and as an aid to prevention of sexually-transmitted diseases (STDs)	The Lifestyles Zero Lubricated Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs)	Yes; minor difference in language of indications statements does not alter intended use
Prescription or Over-The Counter-Use	Over-The-Counter-Use	Over-The-Counter-Use	Yes
Materials	Natural rubber latex	Natural rubber latex	Yes
Form	Straight wall, nipple end	Straight wall, nipple end	Yes
Lubricant Coating	Silicone gel	Silicone gel	Yes
Design	Single use	Single use	Yes
Dimensions	ASTM D3492-15	ASTM D3492-15	Yes
Length	180 +/- 10 mm	180 +/- 10 mm	Yes
Width	52±2 mm	52±2 mm	Yes
Thickness	0.060-080	0.045+/-0.005 mm	Different
Burst Properties	ASTM D3492-15	ASTM D3492-15	Yes

	Predicate Device	**Subject Device**	**Substantial Equivalence**
Air Burst Test Pressure	Minimum 18L	Minimum 18L	Yes
Air Burst Test Volume	Minimum 1 kPa	Minimum 1 kPa	Yes
Leakage AQL	ASTM D3492-15	ASTM D3492-15	Yes
Package integrity AQL	ASTM D3492-15	ASTM D3492-15	Yes
Lubricant Quantity	400-600 mg	400-600 mg	Yes
Sterilization	Non-Sterile	Non-sterile	Yes
Shelf Life	5 years	5 years	Yes
Biocompatibility	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	Yes

The basic technological characteristics of the Lifestyles Zero Lubricated Latex Male Condom are similar to the predicate device. The Lifestyles Zero Lubricated Latex Male Condom and the predicate are made of natural rubber latex, both are straight walled, nipple ended, lubricated condom with an integral ring at the open end. The condom designs conform to the requirements of ASTM D3492:2015 - Standard Specification for Rubber Contraceptives (Male Condoms) and ISO 4074:2015 Natural rubber latex male condoms- Requirements and test methods. The only difference between the subject device and the predicate is the thickness of the condom; 0.040-0.050 mm for this device.

This difference in the technological characteristics does not raise different questions of safety or efficacy in the subject device.

Performance Data:

The subject condom has been tested in conformance with the 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" Guidance for Industry and Food and Drug Administration Staff," issued June 16, 2016. The subject device is indicated for contact with a skin and/or mucosal membrane surfaces for 24 hours or less. Therefore, the device was evaluated for cytotoxicity, irritation, sensitization and acute

systemic toxicity as described below. The condom was demonstrated to be not toxic (local or systemic), sensitizing, or locally irritating.

Cytotoxicity

Lifestyles® Zero® Lubricated Latex Condom was tested per ISO 10993-5 Biological Evaluation of Medical Devices – Part 5, Tests for In Vitro Cytotoxicity

Cytotoxicity test were conducted using the elution method Utilizing serial dilutions of device extract ranged from undiluted to a ratio of 1:32. Severe cytotoxic reactivity was observed for extracts at undiluted and dilutions of 1:2, whereas no cytotoxic reactivity was found for any extracts at lower dilutions.

Such findings are not unexpected for synthetic and natural rubber latexes, and do not necessarily translate to local or systemic toxicity in clinical use. This was the case for the subject condom, where cytotoxic reactions were observed in cell culture assays but there was no evidence of systemic toxicity from the animal studies conducted (as described below).

Irritation and sensitization

Lifestyles® Zero® Lubricated Latex Condom was testing per ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10, Tests for Irritation and Sensitization

Based on the results obtained in the study, it is concluded that the Lifestyles® Zero® Lubricated Male Latex Condom is not considered an irritant or a sensitizer.

Vaginal irritation:
The test article was evaluated for vaginal irritation per ISO 10993-10:2010. The extracts of the test article did not show any signs of vaginal irritation and the average mucosal vaginal irritation scores were within acceptable limits. Test data demonstrates that the device is non-irritating.

Penile irritation:
The test article was evaluated for penile irritation test per ISO 10993-10:2010. No signs of penile irritation were evident macroscopically or microscopically. The penile irritation indices obtained were within the acceptable limit. Test data demonstrates that the device is non-irritating.

Sensitization:
The test article was assessed for sensitization using guinea pig maximization test per ISO 10993-10:2010. Under the conditions of the study, the device was demonstrated to not be a sensitizer.

Acute systemic toxicity

Lifestyles® Zero® Lubricated Latex Condom conforms to the requirements of ISO 10993-11 Biological Evaluation of Medical Devices – Part 11, Tests for Systemic Toxicity.

The test article was evaluated for Acute Systemic Toxicity test. There was no mortality or evidence of systemic toxicity resulted from the test article extract. Test data showed that the test article extract did not show any systemic toxicity.

Physical Testing:

The Lifestyles® Zero® Lubricated Latex Condom was tested and met all the requirements of ASTM D3492-15 Standard Specification for Rubber Contraceptives (Male Condoms).

Shelf Life Testing:

The Lifestyles® Zero® Lubricated Latex Condom has a five-year shelf life based on the results of accelerated stability evaluations conducted as required in 21 CFR 801.435. Five-year expiration dating will be verified with ongoing real time stability evaluations as required in 21 CFR 801.435.

Conclusion:

The subject and predicate devices have the same intended use and similar technological characteristics. The subject device is different from the predicate device in that it is thinner. However, this difference does not raise different questions of safety or effectiveness. The difference was assessed through biocompatibility testing and mechanical performance testing. Performance data demonstrated that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.