DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 18, 2015

O-RING Products LLC
William Mistler
President
4012 Grand Manor Court, #208
Raleigh, NC 27612

Re K150828
Trade/Device Name: O-RING Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: HIS
Dated: November 20, 2015
Received: November 25, 2015

Dear William Mistler,

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,

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)*
K150828

Device Name
O-RING Condom

Indications for Use *(Describe)*

The condom is used for contraceptive 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:

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*"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

**Submitted by:** O-Ring Products, LLC
4012 Grand Manor
Court
Raleigh, NC 27612

**Contact Persons:** William Mistler,
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4012 Grand Manor Court
Raleigh, NC 27612
Tel: 919-327-7186
Email:
wmistler@mac.com

**Date Prepared:** December 14, 2015

**Proprietary Name:** O-Ring Condom

**Common Name:** Male Natural Rubber Latex Condom

**Classification Name:** Condom

**Regulation:** 21 CFR §884.5300

**Product Code:** HIS

**Device Class:** Class II

**Predicate Device:** M.Dior Brand male latex
K083817

**Description of Device:**
This condom is made of a natural rubber latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom design features a patented illuminated ring on the underneath side of the rolled condom. It is lubricated with silicone and cornstarch is used as a dressing material.

This condom is a straight walled with a reservoir tip; nominal length 180mm, nominal flat width 52mm, and nominal thickness 0.07 +/- 0.01 mm.

This condom is designed to conform to established national and international voluntary standards (ISO 4074).

**Intended Use of the Device:**
This natural rubber latex condom has the same intended use as the predicate condom.

The condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases, including HIV.

**Technological Characteristics:**
The 510(k) subject condom, O-RING Condom, has the same technological characteristics as the predicate condom K083817.

**Performance Testing:**
The following performance testing was completed on the subject condom.

**STRENGTH AND INTEGRITY TESTING RESULTS:**

| | |
|---|---|
| Burst Volume | meets ISO 4074 requirements |
| Burst Pressure | meets ISO 4074 requirements |
| Water Leakage | meets ISO 4074 requirements |
| Visual Defects | meets ISO 4074 requirements |
| Package integrity | meets ISO 4074 requirements |

| **BIOCOMPATABILITY TESTS** | **RESULTS** |
|---|---|
| NLI #735574<br>MEM Elution GLP Report | non-cytotoxic |
| NLI #737876<br>ISO Guinea Pig Maximization<br>Sensitization Test GLP | no elicit sensitization response |
| NLI #737877<br>ISO Mucosal (Vaginal)<br>Irritation Test GLP | non-irritant |
| NLI #772222<br>ISO Acute Systemic<br>Injection Test GLP | no signs of toxicity |

**Shelf Life:**
The O-RING Condom has a shelf life of 5 years based on studies conducted per 21 CFR 801.435 guidelines.

**Conclusion:**
The O-RING Condom is substantially equivalent to the proposed predicate device.