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

August 25, 2016

M3 Global Enterprises, LLC
% Lara Luzak
Senior Regulatory Specialist
Registrar Corp.
144 Research Drive
Hampton, VA 23666

Re: K161195
Trade/Device Name: Royal Condoms (Natural, Black Grape, Coffee, Strawberry, and Chocolate Flavors)
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: July 26, 2016
Received: July 27, 2016

Dear Lara Luzak:

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,

For Division

Douglas Silverstein -S
2016.08.25 08:06:18 -04'00'

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)*
K161195

Device Name
Royal Condoms (Natural, Black Grape, Coffee, Strawberry, and Chocolate Flavors)

Indications for Use *(Describe)*
The Royal Condoms are used for contraceptive and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

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.

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510(k) Summary
(K161195)

I. SUBMITTER

M3 Global Enterprises, LLC
70 Birch Alley
Suite 240, Building B
Beavercreek, Ohio 45440
USA
Contact: Neil Mehta
Phone: 1-*937-681-9606*

II. DATE PREPARED: August 24, 2016

III. DEVICE IDENTIFICATION

Name of Device:	Royal Condoms (Natural, Black Grape, Coffee, Strawberry, and Chocolate Flavors)
Common or Usual Name:	Condom
Regulatory Class:	Class II
Regulation:	21 CFR 884.5300
Product Code:	HIS
Classification Panel:	Obstetrics/Gynecology

IV. PREDICATE DEVICE

Trojan Enz Brand Male Latex Condom (K071313)

V. DEVICE DESCRIPTION

The subject condoms are made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. They are single use, non-sterile and available in five versions (natural, black grape, coffee, strawberry and chocolate favored). These condoms are of smooth surface, natural colored in cylindrical shape, straight parallel walled with a reservoir nipple at the closed end and a rim at the open end. These condoms have a minimum length of 182mm, width of 53 - 54mm, and wall thickness between 0.065 - 0.075mm, which comply with ISO 4074.

VI. GUIDANCE DOCUMENT RELIANCE

The submission adheres to the following FDA guidance documents, which were used to support substantial equivalence:

- Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300
- Guidance for Industry: Latex Condoms for Men - Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions

VII. INDICATIONS FOR USE

The Royal Condoms are used for contraceptive and prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject and predicate devices have the same indications. They have the same design and comparable dimensions. Although there are differences in the latex formulations and additives of these devices, the differences do not raise different questions of safety and effectiveness.

IX. PERFORMANCE DATA

Bench Performance: Bench testing demonstrated that the subject condoms met all the requirements of ISO 4074.

Shelf-Life: Results of accelerated shelf-life study support that the subject condoms have a shelf-life of five years from the date of manufacture. The real-time shelf-life study is in progress, as required by 21 CFR § 801.435.

Biocompatibility: The subject condoms have passed the biocompatibility testing in accordance with ODE Guidance Memorandum G95-1 (dated May 1, 1995) and the following standards:

- ISO 10995-5:2009, "Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity"
- ISO 10993-10:2010, "Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization"
- ISO 10993-11:2006, "Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity"
- ISO 10993-12:2012, "Biological Evaluation of Medical Devices - Part 10: Sample Preparation and Reference Materials"

X. CONCLUSIONS

Performance data demonstrate that the subject devices are substantially equivalent to the predicate device in terms of safety and effectiveness.