February 23, 2022

Global Protection Corp.
% Penny Northcutt, FRAPS, RAC
President/CEO
REGSolutions, LLC
174 Watercolor Way, Suite 103-403
Santa Rosa Beach, FL 32459

Re: DEN210034
Trade/Device Name: ONE Male Condom
Regulation Number: 21 CFR§ 884.5305
Regulation Name: External condom for anal intercourse or vaginal intercourse
Regulatory Class: II
Product Code: QRZ
Dated: December 8, 2021
Received: December 9, 2021

Dear Penny Northcutt:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ONE Male Condom, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> The ONE Male Condom is used for contraception to help reduce the risk of pregnancy during vaginal intercourse and for prophylactic purposes to help reduce the transmission of sexually transmitted infections (STIs) during vaginal or anal intercourse. The ONE Male Condom should be used with a condom compatible lubricant when used for anal intercourse.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ONE Male Condom, and substantially equivalent devices of this generic type, into Class II under the generic name external condom for anal intercourse or vaginal intercourse.

FDA identifies this generic type of device as:

> **External condom for anal intercourse or vaginal intercourse.** An external condom for anal intercourse or vaginal intercourse is a barrier device which covers the penis and is used to prevent the transmission of sexually transmitted infections (when used for anal intercourse or vaginal intercourse) and for contraception (when used for vaginal intercourse). This classification does not include condoms intended for vaginal intercourse only.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 26, 2021, FDA received your De Novo requesting classification of the ONE Male Condom. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ONE Male Condom into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the ONE Male Condom can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Transmission of sexually transmitted infection	Acute failure modes clinical study Non-clinical performance testing Shelf life testing Labeling
Pregnancy	Acute failure modes clinical study Non-clinical performance testing Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Mechanical injury leading to ulceration, laceration, trauma	Acute failure modes clinical study Non-clinical performance testing Shelf life testing Labeling
Use error/Improper device use leading to the risks above	Acute failure modes clinical study Labeling

In combination with the general controls of the FD&C Act, the external condom for anal intercourse or vaginal intercourse is subject to the following special controls:

(1) Clinical performance data must demonstrate the total rate of clinical failure and rate of individual failure modes of the device based on an acute failure modes study.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The data must include an assessment of mechanical and material integrity, including an evaluation of device failure modes. For devices made of materials other than natural rubber latex, viral penetration testing must be conducted to evaluate barrier effectiveness to sexually transmitted infections.

(3) The device must be demonstrated to be biocompatible.

(4) Performance data must support the shelf life of the device by demonstrating device functionality and package integrity over the identified shelf life.

(5) Labeling must include:

(i) If indicated for vaginal intercourse, a contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding compatibility with additional lubricant types;

(iii) Statement regarding the adverse events associated with the device, including transmission of infection, pregnancy, adverse tissue reaction, mechanical injury, or improper device use;

(iv) Expiration date; and

(v) The following information, warnings and precautions:

(A) The sexually transmitted infections (STIs) for which the device is most protective, the degree of protection the device provides against specific types of STIs, and the STIs the device does not protect against;

(B) A statement that the device does not completely eliminate the risks of pregnancy and sexually transmitted infections and that risk can be decreased with correct and consistent use;

(C) A warning regarding the risk of device failure during anal intercourse if adequate lubricant is not used;

(D) A warning stating that the device cannot be used multiple times and is limited to one sex act; and

(E) A precaution stating not to use the device if the user is at risk for material related allergic reactions.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the external condom for anal intercourse or vaginal intercourse they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Poulomi Nandy, Ph.D. at (301) 796-7048.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health