February 25, 2022

Okamoto U.S.A. Inc.
% Jeff N. Gibbs
Director
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street N.W., Suite 1200
Washington, DC 20005

Re: K203541
Trade/Device Name: Okamoto 002 Lubricated Polyurethane Male Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: January 25, 2022
Received: January 26, 2022

Dear Jeff N. Gibbs:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) 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 Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

for
Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203541

Device Name
Okamoto 002 Lubricated Polyurethane Male Condom

Indications for Use *(Describe)*
The Okamoto 002 Lubricated Polyurethane 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.

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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"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
K203541
Okamoto 002 Lubricated Polyurethane Male Condom

1. Submitter Information

Applicant: Okamoto USA, INC.
Address: 18 King Street
Stratford, CT 06615
Phone: (203) 378-0003

2. Correspondent Information

Company: Hyman Phelps & McNamara, P.C.
Contact: Jeffrey N. Gibbs
Email: jgibbs@hpm.com

3. Date prepared: February 25, 2022

4. Device Information

Device Name:	Okamoto 002 Lubricated Polyurethane Male Condom
Common Name:	Polyurethane Condom
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	MOL (Condom, Synthetic)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Trojan Supra Lubricated Polyurethane Male Condom
510(k) Number:	K100767
Sponsor:	Church & Dwight Co, Inc.

The predicate device has not been subject to a design-related recall.

6. Device Description

This condom is made of a polyurethane sheath, which completely covers the penis with a closely fitted membrane. This device is a smooth-surfaced, straight-walled, teat-ended, silicone-lubricated condom with nominal length 180 ± 10 mm, nominal width 57 ± 2 mm, and nominal thickness of 0.028 ± 0.008 mm with dimensions evaluated per ISO 23409-2011, Male condoms — Requirements and test methods for condoms made from synthetic materials. This condom also conforms to ASTM D6324-11 (2017) Standard Test Methods for Male Condoms Made from Polyurethane. This product has a shelf life of 5 years. Device specifications are listed in Table 1 below.

7. Indications for Use Statement

The Okamoto 002 Lubricated Polyurethane 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).

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	Subject Device **Okamoto 002 Lubricated Polyurethane Male Condom** **K203541**	**Predicate Device** **Trojan Supra Lubricated Polyurethane Male Condom** **K100767**
Device & Predicate Device	Okamoto 002 Lubricated Polyurethane Male Condom	Trojan Supra Lubricated Polyurethane Male Condom
510(K) Number	K203541	K100767
Product Code	MOL	MOL
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Regulation Name	Condom	Condom
Indications for Use	The Okamoto 002 Lubricated Polyurethane 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).	The TROJAN SUPRA® Lubricated Polyurethane 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).
Prescription or Over-The-Counter Use	Over-The-Counter	Over-The-Counter
Condom Material	Polyurethane	Polyurethane
Nominal Width	57 ± 2 mm	58 ± 2 mm
Nominal Length	180 ± 10 mm	190 ± 10 mm
Nominal Thickness	0.028 ± 0.008 mm	0.040 ± 0.010 mm
Lubricant	Silicone Oil	Silicone Oil
Sterilization	Non-Sterile	Non-sterile
Shape	Straight-walled & Reservoir-ended	Straight-walled & Reservoir-ended
Texture	Smooth Surface	Smooth Surface
Shelf Life	5 Years	5 Years
Color Additives	N/A	N/A
Flavor Additives	N/A	N/A

The subject and predicate device have similar indications for use and have the same intended use. The technological characteristics of the subject and predicate devices are similar in that they are polyurethane-based, are lubricated with silicone oil, and have the same shelf-life duration. The subject and predicate condoms also have identical formulations. There are differences in dimensions and specifications; the subject device has reduced thickness and length compared to the predicate device. These differences do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility:
Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization testing were performed in accordance with the 2020 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" and ISO 10993-1:2009* as follows:

- Cytotoxicity (ISO 10993-5:2009/R 2014)
- Sensitization (ISO 10993-10:2010/R 2014)
- Vaginal Irritation (ISO 10993-10:2010/R 2014)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing demonstrate that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and not acutely, systemically toxic.

Physical Performance Testing:
The subject condom was tested for compliance with the ASTM D6324-11 (2017) Standard Test Methods for Male Condoms Made from Polyurethane for dimensional, tensile strength, force at break, lubricant quantity, visible defects, elongation, air burst volume and air burst pressure requirements. In addition, condoms were tested for tear resistance according to ASTM D624-00 (2020) ("Standard Test Methods for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers") and the 1995 FDA guidance document "Testing Guidance for Male Condoms Made From New Material (Non-Latex)." The subject condom met the predefined acceptance criteria.

Package Integrity:
An evaluation of seal integrity was performed on three lots (3) of the subject device according to ASTM D6324-11 with satisfactory results.

Barrier Properties/Permeability:
A viral penetration study was performed on three (3) test lots of the subject polyurethane condom, one lot of the commercially available predicate device, and a natural rubber latex condom comparator per ISO 23409: 2011. The cumulative results of the studies demonstrate the barrier effectiveness of the subject device as compared to the predicate device and natural rubber latex control condom for viral penetration under conditions of the *in vitro* study.

Shelf Life:
The Okamoto 002 Lubricated Polyurethane Male Condom has a five-year shelf life based on the results of accelerated stability evaluations conducted as required in 21 CFR 801.435 and ASTM D6324-11. All samples met predefined acceptance criteria.

Clinical In-Use Slip/Break:
The sponsor leveraged clinical testing completed on the predicate device to support clinical performance of the subject device. The subject and predicate device have an identical formulation, but dimensionally differ in their thickness and length, as noted in Table 1. The physical performance testing described above demonstrated that the subject device had comparable physical performance to the predicate device, in

regards to tensile strength, force at break, tensile elongation, airburst pressure, airburst volume, and tear resistance. Therefore, clinical testing from the predicate device was leveraged to support the clinical performance of the subject device. A slippage and breakage study following a protocol prepared to meet the FDA guidance "Clinical Testing Guidance for New Material Male Condoms" was conducted using the predicate condom with a standard natural rubber latex condom serving as control. The predicate condom was statistically no different from the control latex condom in both clinical breakage and slippage rate. This testing is adequate to support the clinical slip/break performance for the subject device.

10. Conclusion

The results of the performance testing described above demonstrate that the Okamoto 002 Lubricated Polyurethane Male Condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.