



February 18, 2025

Okamoto USA, Inc.
% Jeff Gibbs
Director
Hyman, Phelps & McNamara, P.C.
700 Thirteenth St. NW
Suite 1200
Washington, District of Columbia 20005

Re: K243584
Trade/Device Name: 0.04 ZERO ZERO FOUR Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: November 20, 2024
Received: November 20, 2024

Dear Jeff 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Monica D. Garcia -S

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

Indications for Use

510(k) Number (if known)

K243584

Device Name

0.04 ZERO ZERO FOUR Male Latex Condom

Indications for Use (Describe)

0.04 Zero Zero Four Male Latex Condom is 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.

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510(k) Summary – K243584

Submitter Name: OKAMOTO USA, INC.

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Date Prepared: February 18, 2025

Trade Name: 0.04 ZERO ZERO FOUR Male Latex Condom

Common Name: Natural rubber latex male condom

Regulation Name: Condom

Regulation Number: 21 CFR 884.5300

Product Code: HIS (condom)

Regulatory Class: Class II

Predicate Device: K140379: Mega Big Boy Condom

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

Description of Device:

The 0.04 ZERO ZERO FOUR Male Latex Condom is a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The subject condom is smooth surfaced with a reservoir tip, silicone lubricated, with a nominal length of 180 mm, nominal flat width of 54 mm, and nominal thickness of 0.042 mm. This condom conforms to current established national standard ASTM D3492: 2016.

Intended Use of the Device:

0.04 Zero Zero Four Male Latex Condom is used for contraceptive and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device:

The table below compares the intended use and technological characteristics of the subject device and predicate device.

	<u>Subject Device</u> 0.04 Zero Zero Four Condom (K243584)	<u>Predicate Device</u> MEGA BIG BOY CONDOM (K140379)	Discussion
Indications for Use	0.04 Zero Zero Four Male Latex Condom is used for contraceptive and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	Mega big boy condom is used for contraceptive and prophylactic purpose (to help prevent pregnancy, hiv/aids and the transmission of sexually transmitted infections).	Similiar
Principal Raw Material of Condom Sheath	Natural Rubber Latex	Natural Rubber Latex	Identical
Color	No color	No color	Identical
Raw Material of Lubricant	Silicone	Silicone	Identical
Shape	Parallel side with Reservoir-ended	Flared shape & Reservoir-ended	Different
Surface Texture	Smooth Surface	Smooth Surface	Identical
Mean Length (mm)	180	200	Different
Mean Width at 30mm from open end (mm)	54	57	Different
Mean Thickness (mm)	0.042	0.063	Different
Air Burst Test Pressure	> 1.0 kPa	> 1.0 kPa	Identical
Air Burst Test Volume	17 dm ³	17 dm ³	Identical
Water Leakage	No leakage	No leakage	Identical
Shelf Life	5 Years	5 years	Identical

The subject device and predicate device have similar indications for use statements and the same intended use – to prevent pregnancy and the transmission of sexually transmitted infections.

The subject and predicate devices have different technological characteristics, including different dimensions and shapes. However, the different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing

Physical Testing: Three (3) lots of 0.04 ZERO ZERO FOUR Male Latex Condom were tested at baseline and met airburst specifications of ASTM D3492-16 Standard Specifications for Rubber Contraceptives (Male Condoms).

Shelf Life: Stability of the 0.04 ZERO ZERO FOUR Male Latex Condom was established from results of physical testing data using a protocol that followed 21 CFR 801.435 and met the requirements of both ASTM D3492-16. Based on the evaluation of the results of the physical testing data, the expiration date has been initially set at 5 years and will be then verified through real-time stability through five (5) years in compliance with FDA expiration labeling requirements in 21 CFR 801.435.

Biocompatibility: Biocompatibility evaluations were performed on the 0.04 ZERO ZERO FOUR Male Latex Condom in accordance 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" dated September 2023.

Table 1: Biocompatibility Evaluations Conducted

Evaluation (biological endpoint)	ISO Standard
Cytotoxicity ISO Elution Method	ISO 10993-5:2009
Vaginal Irritation	ISO 10993-23:2021
Guinea Pig Maximization Sensitization	ISO 10993-10:2021
Acute Systemic Toxicity	ISO 10993-11:2017

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

Conclusion:

Based on the results of the non-clinical testing described above, the 0.04 ZERO ZERO FOUR Male Latex Condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.