May 4, 2026

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

Re: K252622
Trade/Device Name: Male Latex Condom HA
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: August 19, 2025
Received: April 3, 2026

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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)*
K252622

Device Name
Male Latex Condom HA

Indications for Use *(Describe)*
The Male Latex Condom HA is used for contraceptive and prophylactic purposes (preventing 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 – K252662

I. Submitter Information

Submitter Name: OKAMOTO USA, INC.

Submitter Address: 3130 West Monroe Street Sandusky OH 44870 United States

Submitter Contact Person: Mr. Kenji Komatsu
Phone: 973-261-9055
E-mail: kenjikomatsu@okamotousa.com

Preparer Name: Mr. Jeff Gibbs
Hyman, Phelps & McNamara, P.C.
700 Thirteenth St. NW Suite 1200 Washington DC 20005 United States
Phone: 202-737-4288
E-mail: jgibbs@hpm.com

II. Date Prepared: May 4, 2026

III. Subject Device Information

Trade Name: Male Latex Condom HA

Common Name: Natural rubber latex male condom

Regulation Name: Condom

Regulation Number: 21 CFR 884.5300

Product Code: HIS (condom)

Regulatory Class: Class II

IV. Predicate Device

Submission Number: K192669

Device Trade Name: Extremely Thin 003, ZERO ZERO THREE

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

V. Description of Device

The Male Latex Condom HA is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane.

This device is a smooth-surfaced, straight-walled, teat-ended, water-based natural rubber condom with a water-based lubricant that includes hyaluronic acid. It has a nominal length of 180 mm, nominal width of 53.5 mm, and nominal thickness of 0.04 mm. This condom conforms to the currently recognized standard ASTM D3492: 2016.

VI. Indications for Use:

The Male Latex Condom HA is used for contraceptive and prophylactic purposes (preventing transmission of sexually transmitted infections).

VII. 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.

	Subject Device Male Latex Condom HA (K252662)	**Predicate Device** Extremely Thin 003, ZERO ZERO THREE (K192669)	**Discussion**
Indications for Use	The Male Latex Condom HA is used for contraceptive and prophylactic purposes (preventing transmission of sexually transmitted infections).	The condom is used for contraception and for prophylactic purposes (preventing transmission of sexually transmitted infections.)	Identical
Principal Raw Material of Condom Sheath	Natural Rubber Latex	Natural Rubber Latex	Identical
Color	No color	No color	Identical
Raw Material of Lubricant	Water-based with hyaluronic acid lubricant	Silicone	Different
Shape	Straight-walled & Reservoir-ended	Straight-walled & Reservoir-ended	Identical
Surface Texture	Smooth Surface	Smooth Surface	Identical
Nominal Length (mm)	180 ± 10 mm	180 ± 10 mm	Identical
Nominal Width at 30mm from open end (mm)	53.5 ± 2 mm	53.2 ± 2 mm	Similar
Nominal Thickness (mm)	0.04 ± 0.01 mm	0.04 ± 0.01 mm	Identical
Air Burst Test Pressure	> 1.0 kPa	> 1.0 kPa	Identical
Air Burst Test Volume	> 18 L (dm^3)	> 18 L (dm^3)	Identical
Water Leakage	No leakage	No leakage	Identical
Shelf Life	5 Years	5 years	Identical

The subject device and predicate device have the same 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 (e.g., formulation, lubricant and dimensions). These differences do not raise different questions of safety and effectiveness.

VIII. Summary of Non-Clinical Performance Testing

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

Shelf Life: Stability of the Male Latex Condom HA 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 and ISO 4074:2015. 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 Male Latex Condom HA 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. The biocompatibility evaluations conducted, and the applicable ISO standards are listed below:

- Cytotoxicity Elution Method ISO 10993-5:2009
- Guinea Pig Maximization Sensitization ISO 10993-10:2021, ISO 10993-12:2021
- Vaginal Irritation ISO 10993-23:2012, ISO 10993-12:2021
- Acute Systemic Toxicity ISO 10993-11:2017, ISO 10993-12: 2021

The results of these evaluations demonstrate that the subject device is non-irritating, non-sensitizing, and non-cytotoxic.

IX. Conclusion:

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