



March 30, 2026

Mayer Laboratories  
David P. Mayer  
President  
1400 Shattuck Ave., Suite 9  
Berkeley, CA 94709

Re: K252158  
Trade/Device Name: Sagami Original 002 Polyurethane Male Condom  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: MOL  
Dated: July 8, 2025  
Received: July 9, 2025

Dear David P. Mayer:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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](mailto: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)  
K252158

Device Name  
Sagami Original 002 Polyurethane Male Condom

Indications for Use (Describe)

Sagami Original 002 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)

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### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) Summary**  
**K252158**  
**Sagami Original 002 Polyurethane Male Condom**

**1. Submitter Information**

Applicant: Mayer Laboratories  
Address: 1400 Shattuck Ave Suite 9  
Berkeley, CA 94709  
Phone: (501) 229-5300

**2. Correspondent Information**

Company: Mayer Laboratories  
Contact: David P. Mayer, President  
Email: [davidm@mayerlabs.com](mailto:davidm@mayerlabs.com)

**3. Date prepared:** March 30, 2026

**4. Device Information**

Device Name: Sagami Original 002 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: Okamoto 002 Lubricated Polyurethane Male Condom  
510(k) Number: K203541  
Sponsor: Okamoto U.S.A Inc.

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

**6. Device Description**

The Sagami Original 002 Polyurethane Male Condom is made of a closely fitted sheath with a closed end, which completely covers the male penis with a non-latex, impermeable, non-sterile, fitted membrane made of a polyurethane material. Each device in the family is made of the same material: Polyurethane. All devices have a smooth-surface with a straight/parallel-walled shape, with a closed end that has a reservoir tip. Each device is lubricated with silicone oil (“dimethylpolysiloxane”) and individually packaged. The Sagami Original 002 Condoms are a non-sterile, single use device. They are for home use and environments where persons have sexual activity. Based on currently available stability information, Sagami Original 002 Slim Fit and Sagami Original 002 Regular Mayer Labs have a 5 year shelf life and Sagami Original 002 Large has a 3 year shelf life.

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## 7. Indications for Use Statement

Sagami Original 002 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.

	<b>Subject Device Sagami Original 002 Polyurethane Male Condom K252158</b>	<b>Subject Device Okamoto 002 Lubricated Polyurethane Male Condom K203541</b>	<b>Comparison</b>
<b>Device &amp; Predicate Device</b>	Sagami Original 002 Polyurethane Male Condom	Okamoto 002 Lubricated Polyurethane Male Condom	--
<b>510(K) Number</b>	K252158	K203541	--
<b>Product Code</b>	MOL	MOL	Same
<b>Regulation Number</b>	21 CFR 884.5300	21 CFR 884.5300	Same
<b>Regulation Name</b>	Condom	Condom	Same
<b>Indications for Use</b>	Sagami Original 002 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 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).	Same
<b>Prescription or Over-The-Counter Use</b>	Over-The-Counter	Over-The-Counter	Same
<b>Condom Material</b>	Polyurethane	Polyurethane	Same
<b>Nominal Width</b>	Slim fit: 55 ± 2 mm Regular: 58 ± 2 mm Large: 61 ± 2 mm	57 ± 2 mm	Different
<b>Nominal Length</b>	Slim fit: 170 ± 10 mm Regular: 190 ± 10 mm Large: 190 ± 10 mm	180 ± 10 mm	Different
<b>Nominal Thickness</b>	Mid-body: 0.024 ± 0.008 mm	0.028 ± 0.008 mm	Different
<b>Lubricant</b>	Silicone Oil	Silicone Oil	Same
<b>Lubricant Quantity</b>	400 ± 100 mg	400 ± 40 mg	Different
<b>Air Burst Pressure</b>	Not less than 2.0 kPa	Not less than 1.8 kPa	Different
<b>Air Burst Volume</b>	Not less than 3.6 dm <sup>3</sup>	Not less than 4.0 dm <sup>3</sup>	Different
<b>Sterilization</b>	Non-Sterile	Non-Sterile	Same

<b>Shape</b>	Straight-walled & Reservoir-ended	Straight-walled & Reservoir-ended	Same
<b>Texture</b>	Smooth Surface	Smooth Surface	Same
<b>Shelf Life</b>	Slim fit, regular: 5 Years Large: 3 Years	5 Years	Different
<b>Color Additives</b>	N/A	N/A	Same
<b>Flavor Additives</b>	N/A	N/A	Same

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 a surface medical device with limited contact duration (<24 hr contact with skin and mucosal membranes) per the 2023 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"* 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 ISO 23409:2011, "Male Condoms – Requirements and test methods for condoms made from synthetic materials, " "Guidance for Male Condoms Made from New Material (Non-Latex), issued by the FDA in June 1995, and meets requirements of ISO 4074:2015, "Natural rubber latex male condoms – Requirements and test methods" for dimensional, tensile strength, force at break, lubricant quantity, visible defects, tear resistance and propagation, elongation, air burst volume and air burst pressure requirements.

### Package Integrity:

An evaluation of seal integrity was performed on three lots (3) of the subject device according to ISO 23409: 2011 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 Sagami Original 002 Polyurethane Male Condom has a shelf life based on the results of accelerated stability evaluations conducted as required in 21 CFR 801.435 and ISO 23409:2011. Based on the currently available, stability information, Mayer Labs is claiming a 5 year shelf life on Sagami Original 002 Slim Fit and Sagami Original 002 Regular, and a 3 year shelf life on Sagami Original 002 Large.

All samples met predefined acceptance criteria.

**Clinical In-Use Slip/Break:**

Clinical testing was performed. The Study design complied with the recommendations of the FDA guidelines for clinical studies on synthetic condoms and ISO 29943 -1:2017. The Study is registered on the clinicaltrials.gov website with the identifier NCT04622306. The slippage and breakage study, which conforms to ISO 23409: 2011 and follows a protocol prepared to meet the FDA guidance "Testing Guidance for Male Condoms Made From New Material (Non-Latex)" June 1995, was conducted. Condom Polyurethane A, representative of the Sagami Original 002 Polyurethane Male condom, met the noninferiority requirements specified in ISO 23409:2011 and demonstrated low failure rates relative to a standard natural rubber latex condom as a comparator in the full study population.

**10. Conclusion**

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

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