July 24, 2020

Okamoto U.S.A., Inc.
% Jeffrey N. Gibbs
Official Correspondent
Hyman, Phelps & McNamara, P.C.
Washington, DC 20005

Re: K192669
Trade/Device Name: Extremely Thin 003, ZERO ZERO THREE
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: June 25, 2020
Received: June 26, 2020

Dear Jeffrey 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,

Jason R. Roberts, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192669

Device Name
Extremely Thin 003, ZERO ZERO THREE

Indications for Use *(Describe)*
The condom is used for contraception and for 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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"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

Submitted by:	OKAMOTO U.S.A., INC. 18 King Street Stratford, CT 06615 Phone: 203-378-0003
Contact Person:	Jeffrey N. Gibbs, Hyman Phelps & McNamara, P.C. Yu Tadano, Okamoto USA., Inc.
Date Prepared:	July 23, 2020
Device/Trade Name:	Extremely Thin 003, ZERO ZERO THREE
Common Name:	Male Latex Condom
Product code:	HIS
Classification Name:	Condom (21 C.F.R. § 884.5300)
Predicate Device:	
Brand Name:	OKAMOTO ULTRA THIN Male Natural Latex Condom, now marketed as 0.04 ZERO ZERO FOUR®
Company Name:	OKAMOTO U.S.A., INC.
Predicate Device 510(k) Document Control Number:	K090259

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

Description of the Device:

The device is a condom that 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, silicone-lubricated condom with nominal length 180 ± 2mm, nominal width 53.5 ± 2mm, and nominal thickness of 0.04 mm. This condom conforms to the recognized standards ASTM D3492-16 and ISO 4074:2015.

Indications for Use of the Device:

The condom is used for contraception and for prophylactic purposes (preventing transmission of sexually transmitted infections).

The subject device indications for use are identical to that of the predicate.

Technological Characteristics:
The subject condom has the same technological characteristics as the predicate condom, differing in the compounded latex formulation and having minor dimensional differences. The design of this condom is in conformance with ASTM Standard D3492-16 Specification for Rubber Contraceptives (Male Condoms), and the condoms are made of natural rubber latex.

The following comparison table summarizes the similarities and differences of the features and technological characteristics of the condom in comparison to the predicate condom.

Table 1 – Summary of Similarities and Differences

Characteristics	**Proposed Condom**	**Predicate Condom K090259**	
Indications for Use	The condom is used for contraception and for prophylactic purposes (preventing transmission of sexually transmitted infections.)	The condom is used for contraception and for prophylactic purposes (preventing transmission of sexually transmitted infections.)	Same
Condom Material	Natural rubber latex	Natural rubber latex	Same
Nominal Width	53.2 ± 2 mm	54 ± 0.3 mm	Different
Nominal Length	180 ± 10 mm	184 ± 1.5 mm	Different
Nominal Thickness	30 mm from closed end: 0.039 ± 0.0013 90 mm from closed end: 0.039 ± 0.001 150 mm from closed end: 0.039 ± 0.001	30 mm from closed end: 0.042 ± 0.0014 90 mm from closed end: 0.043 ± 0.0012 150 mm from closed end: 0.045 ± 0.001	Different
Lubricant	Silicone	Silicone	Same
Color Additives	No color	No color	Same
Flavor Additives	No flavor	No flavor	Same
Shape	Straight-walled & reservoir-ended	Straight-walled & reservoir-ended	Same
Texture	Smooth surface	Smooth surface	Same
Bursting Pressure (kPa)	1.42 ± 0.10	1.33 ± 0.12	Different
Bursting Volume (dm3)	35.4 ± 3.83	37.2 ± 4.28	Different
Shelf-life	5 years	5 years	Same

As noted in the table above, the technological characteristics of the subject device

and predicate are similar in that they are natural rubber latex-based, do not contain colorants, and are pre-lubricated with silicone oil. Differences between the subject and predicate device include dimensions of the condoms (e.g., width and thickness), formulation and burst pressure. The subject and predicate condom specifications lie within the specifications of ASTM D3492-16 and ISO 4074:2015. The differences in condom dimensions do not raise different questions of safety and effectiveness as compared to the predicate device.. The difference in ingredients also does not raise different questions of safety and effectiveness. The differences can be evaluated through biocompatibility and performance testing.

Summary of Performance Testing

- Biocompatibility testing was conducted as follows:
  - Cytotoxicity testing per ISO 10993-5:2009
  - Guinea pig maximization sensitization testing per ISO 10993-10:2010
  - Vaginal irritation testing per ISO 10993-10:2010
  - Acute systemic toxicity testing for ISO 10993-11:2006

The device was demonstrated to be biocompatible.

- Physical Testing Data: Three lots of devices were tested at baseline and met airburst specifications of ISO 4074:2015 – Natural rubber latex male condoms – Requirements and test methods and ASTM D3492:2016 – Standard Specification for Rubber Contraceptives (Male Condoms).

- Shelf Life: Stability testing to support a shelf-life of five years per the requirements of 21 CFR §801.435 was conducted. All samples met predefined acceptance criteria.

Conclusion:
Based on the results of the testing and safety data described above, the Extremely Thin 003, ZERO ZERO THREE male natural rubber latex condom is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate.