JUL 2 3 2014

II. *510(k) SUMMARY*

Submitted by: OKAMOTO U.S.A., INC.
3130 West Monroe Street
Sandusky, OH 44870
Phone: 419-626-1633

Contact Person: Joseph W. Cormier, JD, PhD / Hyman, Phelps & McNamara
Mr. Hirofumi Chiba, Okamoto USA., Inc.

Date Prepared: July 21, 2014

Proprietary Name: Okamoto Studded Condom

Common Name: Male Latex Condom

Classification Name: Condom (21 C.F.R. § 884.5300)

Predicate Device:

1) Brand Name: BillyBoy Dotted (Beaded) condom
Company Name: MAPA GmbH
510(k) Document Control Number: K111093

Description of the Device:

This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom is textured surface (dotted), tapered shape with reservoir tip, silicone lubricated condom with nominal length 180 mm, nominal flat width 54 mm measured at 30 mm from the open end, a maximum width of 58 mm at the closed end, and nominal thickness of 0.070 mm. The air burst pressure is $\geq$ 1 kPa and air burst volume is $\geq$ 17 dm^3. It is lubricated with silicone (viscosity 200 cps) and cornstarch is used as a dressing material. This condom conforms to current established national standard ASTM D3492: 2008.

The term Studded refers to the irregular surface of the condom. The irregular surface is not applied externally but is achieved in the molding process. The glass mold has an engraved pattern of semispherical pits replicated as a pattern of small round tips on the surface of the

condom. This results in an exterior surface that has a pattern of small raised areas best described as a dotted pattern. The new condom is defined as a condom of increased thickness relative to some of other Okamoto condoms (e.g., Crown condom, K893039).

Intended Use of the Device:

This Okamoto Studded condom is used for contraceptive and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Technological Characteristics:

The subject condom has nearly identical technological characteristics to the predicate condom. It is identical in terms of additives and manufacturing process. The subject and predicate condoms have the same indications for use. As indicated in the table below, the only differences are the shape, nominal width and length, the quantity of lubrication, and the latex formulation. These differences do not affect the safety or effectiveness or affect performance of the subject condom as compared to the predicate. Testing on the subject condom demonstrates conformance with ISO 10993, Biological Evaluation of Medical Devices for a device in contact for 24 hours or less for cytotoxicity, irritation and sensitization, acute systemic toxicity testing, and sample preparation and reference material. Testing shows these condoms are non-toxic, non-sensitizing, and non-irritating. Stability studies conducted on the similar condoms established a shelf life of the device at 5 years. The differences in dimension, latex formulation, and quantity of lubrication do not affect cytotoxicity, irritation, sensitization, or shelf life. Furthermore, because the differences in characteristics are common for natural rubber latex male condoms, the differences do not raise new questions of safety or effectiveness.

The results of biocompatibility testing for cytotoxicity, irritation and sensitization, and acute systemic toxicity as well as airburst testing demonstrate that the subject device is substantially equivalent to the predicate device in term of safety and effectiveness.

The similarities and differences of the features and technological characteristics of the condom as compared to the predicate condom are shown in the table below.

Table 1- Characteristics of Submission Device and Predicate Device

	Submission device: Okamoto Studded Male Latex Condom	**Predicate device: Billy Boy Male Latex Condom, K111093**
FDA Classification	Class II; 884.5300	Identical
Classification code	HIS	Identical
Intended Use	For contraceptive and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	Identical
Material	Natural rubber latex	Identical
Performance	Complied with ASTM D3492:2008	Identical
Type	Dotted	Dotted (beaded)
Shape	Tapered shape with reservoir tip; dotted	Straight walled with reservoir tip; cylindrical; dotted/beaded
Length	170-190 mm	> 175 mm
Width	54 ± 2 mm measured 30 mm from open end, Maximum width of 58 ± 2 mm at the closed end	52 mm
Thickness	0.070 ± 0.010 mm	0.100 ± 0.010 mm
Lubricant	0.550 g silicone oil	0.49 g silicone oil
Color	None	Identical
Scent	None	Identical
Latex Formulation	Natural Rubber Latex	Comparable
Dusting Agent	Cornstarch and MgO	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 23, 2014

Okamoto USA, Inc.
% Joseph W. Cormier
Law Offices of Hyman, Phelps
& McNamara, P.C.
700 Thirteenth Street N.W., Suite 1200
Washington, DC 20005-5929

Re: K141256
Trade Name: Okamoto Studded Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: May 14, 2014
Received: May 14, 2014

Dear Joseph W. Cormier,

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. 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 (21CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301)796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141256

Device Name
Okamoto Studded Condom

Indications for Use *(Describe)*

The Okamoto Studded 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.07.23 15:57:22 -04'00'

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."