II. 510(k) SUMMARY

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

Contact Person: Mr. Hirofumi Chiba, Okamoto USA., Inc.

Date Prepared: June 25, 2014

Proprietary Name: Mega Big Boy Condom

Common Name: Male Latex Condom

Classification Name: Condom (21 CFR §884.5300)

Predicate Device:
Brand Name: TROJAN EXTRA LARGE LATEX CODOM
Company Name: Church & Dwight Co., Ltd.
510(k) Document Control Number: K001212

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 smooth surface, flared at the closed end with reservoir tip, silicone lubricated condom with nominal length 200 mm, nominal flat width 57 mm, and nominal thickness of 0.065 mm. The air burst pressure is $\geq$ 1 kPa and air burst volume is $\geq$ 19 dm^3. It is lubricated with silicone (viscosity 350 cps) and cornstarch is used as a dressing material. This condom conforms to current established national standard ASTM D3492: 2008.

Intended Use of the Device:
This latex condom has the same intended use as the predicate condom. This Mega Big Boy condom is used for contraceptive and prophylactic purposes (to help prevent pregnancy, HIV/AIDS 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 manufacturing process. As indicated in the table below, the only differences from the user's perspective are the mean length and thickness. These differences do not affect the safety or effectiveness or affect performance of the subject condom as compared to the predicates. Testing on condoms differing only with respect to dimensions is conducted to demonstrate 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, and sample preparation and reference material. Testing also shows these condoms are non-toxic, non-sensitizing, and non-irritating. Stability studies were conducted to establish shelf life of the device at 5 years. The differences in dimension do not affect cytotoxicity, irritation, sensitization, acute systemic toxicity, or shelf life.

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

Item	Submission Device	Similar Device in US market
Brand Name	MEGA BIG BOY	TROJAN® MAGNUM XL
510(k) Number	K140379	K001212
Manufacturer	OKAMOTO RUBBER PRODUCTS CO., LTD.	CHURCH & DWIGHT CO., INC.
Common Name	Male Latex Condom	Male Latex Condom
FDA Classification Name	Condom (21 CFR §884.5300)	Condom (21 CFR §884.5300)
Indications for Use	To be used for contraceptive and prophylactic purposes (to help prevent pregnancy, HIV/AIDS and the transmission of sexually transmitted infections).	To be used for contraceptive and prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs) by men who feel that current regular and larger sized condoms are too small.
Principal Raw Material of Condom Sheath	Natural Rubber Latex	Natural Rubber Latex
Color	No color	No color
Raw Material of Lubricant	Silicone	Silicone
Shape	Tapered wall & Reservoir-ended	Tapered wall & Reservoir-ended
Surface Texture	Smooth Surface	Smooth Surface
Mean Length (mm)	200	194
Mean Width (mm) at 30mm from open end	57	57
Mean Thickness (mm) at 80mm from open end	0.063	0.081
Shelf Life	5 Years	5 Years

All product testing demonstrates that the device is in conformance with all relevant performance standards, and that the device is expected to be safe for its intended use. The subject device characteristics and intended use are identical or very similar to the referenced predicate device. Accordingly, the subject device is substantially equivalent to the predicate device.

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 1, 2014

Okamoto USA, Inc.
% Jeffrey N. Gibbs
Director
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, DC 20005

Re: K140379
Trade/Device Name: Mega Big Boy Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: June 4, 2014
Received: June 4, 2014

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. 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,

Herbert P. Lerner -S

for

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)*
K140379

Device Name
Mega Big Boy Condom

Indications for Use *(Describe)*
Mega Big Boy condom is used for contraceptive and prophylactic purpose (to help prevent pregnancy, HIV/AIDS 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)*

Herbert P. Lerner -S
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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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