K090259

510(k) SUMMARY

MAR 31 2009

Submitted by: OKAMOTO U.S.A., INC.
18King Street
Stratford, CT 06615
Phone: 203-378-0003

Contact Person: Mr. Jeffery N. Gibbs, Esq., Hyman Phelps & McNamara
Ms. Jennifer Calderon, Okamoto USA., Inc.

Date Prepared: December 1, 2008

Proprietary Name: OKAMOTO ULTRA THIN

Common Name: Male Latex Condom

Classification Name: Condom (21 CFR §884.5300)

Predicate Device:

1) Brand Name: BEYOND SEVEN®, CROWN®
Company Name: OKAMOTO INDUSTRIES, INC.
510(k) Document Control Number: *K872812/A*
**Beyond Seven® and Crown® are under the same 510(k) Number.*

2) Brand Name: KIMOTO MICRO THIN®
Company Name: SAGAMI RUBBER INDUSTRIES CO., LTD.
510(k) Document Control Number: K946374

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 device is smooth surfaced, straight-walled, teat-ended, silicone lubricated condom with minimum length 160mm, maximum width 54mm, and minimum thickness of 30μm as required by ASTM Standard D3492.

Intended Use of the Device:

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

Reason for 510(k) submission:

The nominal thickness of the currently marketed product is 0.05+/-0.01mm. Recently the market is demanding thinner condoms, and therefore, we decided to submit a new 510(k) for thinner condoms with nominal thickness of 0.04+/-0.01mm.

Technological Characteristics:

The subject condom has the same technological characteristics as the predicate condoms.
The design of this condom is in conformance with ASTM Standard D3492-03 Specification for Rubber Contraceptives (Male Condoms) and the condoms are made of natural rubber latex.
The comparison with the predicate condoms is provided in Exhibit #1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2009

Okamoto USA, Inc.
c/o Jeffrey N. Gibbs, Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
WASHINGTON DC 20005

Re: K090259
Trade/Device Name: OKAMOTO ULTRA THIN Male Natural Latex Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: January 30, 2009
Received: February 2, 2009

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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; 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K090259

Device Name: OKAMOTO ULTRA THIN Male Natural Latex Condom

Intended Use of the Device:

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓

(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090259