II. 510(k) SUMMARY

Submitted by:

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Contact Person:

David P. Mayer, President
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Date Prepared:

December 12, 2011

Proprietary Name:

Kimono MicroThin with Aqua Lube
Reality Ultra Lubricated

Common Name:

Latex Condom

Classification Name:

Condom (21 CFR §884.5300)

Predicate Device:

Kimono MicroThin
510(k) number: K946374
Orion/XT-12
510(k) number: K872356/B
Original 510(k) submission clearance attached as Attachment 5.

Description of Device:

This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom is lubricated by a water based lubricant system.

Typical (Average) Product Characteristics are as follows:

- Straight walled, reservoir end
- Nominal length (mm): 190mm+/-10mm
- Nominal width (mm): 52 mm +/- 2mm
- Nominal thickness (mm) .04 -0.01
  Kimono MicroThin with Aqua Lube:
  .049mm +/- 0.01
  Reality Ultra Lubricated: .065mm +/- 0.01mm

***510(k) SUMMARY** (continued)*

Intended Use:	This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)
Technological Characteristics:	The basic design, composition (natural rubber latex) and manufacturer of these condoms are the same as the predicate male latex condoms, except that these condoms are lubricated with a water based lubricant system. The condom design conforms to the current edition of national and international standards: ASTM D3492 and ISO 4074. All physical testing, air inflation testing, and other in-process and final release testing revealed results in conformance with required standards and Company specifications. Accordingly, when compared to the predicate male latex condoms, the condoms intended to be introduced do not incorporate any significant changes in intended use, method of operations, materials, or design that could affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. David P. Mayer
President and CEO
Mayer Laboratories, Inc.
1950 Addison Street, Suite 101
BERKELEY CA 94704

MAR - 6 2012

Re: K113686
Trade/Device Name: Kimono MicroThin with Aqua Lube / Reality Ultra Lubricated/Male Natural Rubber Latex Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: February 23, 2012
Received: February 28, 2012

Dear Mr. 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 (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 (21 CFR 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (21 CFR 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 Small Manufacturers, International and Consumer Assistance 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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: _K113686_____

Device Name: Kimono MicroThin with Aqua Lube / Reality Ultra Lubricated/Male Natural Rubber Latex Condom

Indications For Use: Kimono MicroThin with Aqua Lube / Reality Ultra Lubricated condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

(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____X_____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113686