K103119
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II. 510(k) SUMMARY

FEB 24 2011

Submitted by: MAPA GmbH
Industriestrasse
Zeven Germany
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Contact Person: German Frank, Director of Quality Management

Date Prepared: February 23, 2011

Proprietary Name: Billy Boy Male Latex Condoms

Common Name: Latex Condom

Classification Name: Condom (21 CFR §884.5300) Code HIS

Predicate Devices:

Manufacturer	Device Name	Applicable 510(k) #	SE
Dalian Latex Company Ltd.	Twin Lotus Male Latex Condoms	K081413	Yes
Mayer Laboratories	Kimono Maxx	K943064, K904375	Yes
Church & Dwight co., Inc. and Armkel, llc.	Trojan Her Pleasure	K073016, K071313, K071272, K023405	Yes

Description of the Device: The BillyBoy condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The condom is shaped with a reservoir end and is Cylindrical. These condoms have a length of 175 - 185mm ±10mm, a width of 52.0 -55.0 mm ±2.0mm. The thickness is 0.04-0.08 mm. The air burst test pressure is ≥1 k Pa and air burst test volume is ≥18 dm^3. The primary packaging material is a foil package. The on surface lubricant is silicon oil.

Intended Use of the Device: The Billy Boy condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections). The condoms are available in cylindrical shape in transparent color and with Nivesse aroma. The models include the BillyBoy, BillyBoy Scented, BillyBoy Special Comfort and BillyBoy Extra Lubricated.

Technological Characteristics: The tables below show that the submission device has the same core technological characteristics as the predicate condoms identified above. The design of the submission device is in conformance with ASTM Latex Condom Standard D3492 and is made of natural rubber latex. The similarities and differences of

the features and technological characteristics of the condom are compared to the predicate condoms below.

Table 2 - BillyBoy Substantial Equivalence Comparison to the Twin Lotus Male Latex Condom

	Predicate Device **Twin Lotus Male Latex Condoms** **K081413**	**Submission Device** **Billy Boy** **Male Latex Condoms**
FDA classification	Class II §884.5300	Class II §884.5300
Classification Code	HIS	HIS
Intended Use	The device is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).	The Billy Boy condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections)
Material	Natural Latex Rubber	Natural Latex Rubber
Biocompatibility	Compliant with ISO 10993	Compliant with ISO 10993
Performance	Compliant with ASTM D3492	Compliant with ASTM D3492
Types	Plain, Dotty, Ribbed, Combination	Cylindrical
Shape	Straight walled with reservoir tip	Straight walled with reservoir tip
Length	160mm	185mm ±10mm
Width	52 ± 2mm	52.0mm ±2.0mm
Thickness	0.08 ± 0.01 mm	0.04-0.08mm
Color	Red, yellow, green, blue, violet, black, orange	Natural (transparent)
Flavor	Banana, Strawberry, Orange, Chocolate, Mint, Vanilla, Juicy Peach, Pineapple, Apple, Cherry	Nivesse (scent)

Table 3 – Substantial Equivalence of the width of the Billy Boy Special Comfort flared shank version to the Kimono Maxx and Trojan Her Pleasure.

	Billy Boy Special Comfort	Kimono Maxx	Trojan Her Pleasure
FDA Classification	Class II § 884.5300	Class II § 884.5300	Class II § 884.5300
Classification code	HIS	HIS	HIS
Material	Natural latex rubber	Natural latex rubber	Natural Rubber Latex
Shape	contoured shape with reservoir	contoured shape with reservoir	Comfort shape Tapered Base w/ Reservoir Tip
Length	≥175 mm	195 mm	205
Flat Width (at 30 mm)	(55 ± 2) mm	52 mm	55mm
Max. width	(61.5 ± 2) mm	59 mm	65mm
Narrowest flat width	(55 ± 2) mm	52 mm	55mm
Thickness	0.04-0.08 mm	0.07 mm	0.07mm

Comparison of Dimensions

These additional natural latex rubber condom predicates demonstrate that the maximum width of the Billy Boy Special Comfort flared shank version falls in between that of two predicate devices (Kimono Maxx and Trojan Her Pleasure) that have been cleared and that are commercially available in the US. The width at 30mm and at the narrowest flat width for the BillyBoy Special Comfort is the same as the widths for the Trojan Her Pleasure. As the maximum width is smaller and all other widths and thickness dimensions are the same or similar to the Trojan Her Pleasure, the Billy Boy Special Comfort flared version should not affect slippage or breakage. Therefore, the Billy Boy Special Comfort does not raise new issues of safety or effectiveness as their dimensions are substantially equivalent to the Trojan Her Pleasure.

Discussion of Similarities and Differences

As can be seen from the comparison tables above, the devices have the same basic technology, the same intended use and are compliant with the same recognized and required standards. Also specific length and width dimensions of the BillyBoy are substantially equivalent to those of other legally marketed devices.

Performance Data

The functional testing of male condoms is conducted according to ASTM D3492. Like the predicate devices, BillyBoy condoms were tested to the standard and passed all required specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

MAPA GmbH
c/o Mr. Mark A. Job
Responsible Third Party
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

FEB 24 2011

Re: K103119
Trade Name: Billy Boy Male Latex Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product code: HIS
Dated: February 4, 2011
Received: February 7, 2011

Dear Mr. Job:

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,

Herbert P. Lerner, M.D., Director (Acting)
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: (if known) K103119

Device Name: The Billy Boy Male Natural Rubber Latex Condom

Indications For Use: The Billy Boy condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections). The condoms are available in Cylindrical shape, in transparent color and with Nivesse aroma. The models include the BillyBoy, BillyBoy Scented, BillyBoy Special Comfort and BillyBoy Extra Lubricated.

Prescription Use _____ OR Over-The-Counter Use_____X_____
(Per 21 CFR §801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103119