510(k) Summary

JUN - 3 2011

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

Date Prepared: March 24, 2011; revised June 1, 2011

Proprietary Name: BillyBoy Dotted (Beaded) Condom;
BillyBoy New Condom

Common Name: Latex Condom

Classification Name: Condom (21 CFR §884.5300)

Predicate Devices:

Device	Mfg	K #
Billy Boy condoms	MAPA GmbH	K103119
SLAM Condom manufactured by;	Nippon Rubber Industry	K011253
Lifestyles Extra Strength) Ultra Thick Male Latex Condom	Ansell Inc.	K871304

Description of the Device: This 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 flat with a cylindrical shape. These condoms have a length of ≥175mm, a width of 52mm. The thickness is 0.10 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. The term Dotted 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 the other BillyBoy types.

Intended Use of the Device: The BillyBoy male latex condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections). The BillyBoy condoms are Dotted/Beaded and New Condom models.

Technological Characteristics: The table below shows that the submission device has the similar 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 is compared to the predicate condoms below.

	Predicate Device **Billy Boy** **Male Latex Condoms** **BillyBoy, BillyBoy Scented; BillyBoy Special Comfort and BillyBoy Extra Lubricated** **K103119**	**Submission Device** **Billy Boy** **Male Latex Condoms** **Dotted (Beaded); New Condom**
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 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	The BillyBoy male latex condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections). The BillyBoy condoms are Dotted/Beaded and New Condom models.
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	BillyBoy, BillyBoy Scented; BillyBoy Special Comfort and BillyBoy Extra Lubricated	Dotted (Beaded); New Condom
Shape	Straight walled with reservoir tip; Flared or Cylindrical	Straight walled with reservoir tip; Cylindrical; Cylindrical Dotted / Beaded
Length	185mm ±10mm	≥175mm
Width	52.0mm ±2.0mm	52mm
Thickness	0.04-0.08 mm.	0.10mm.
Lubricant	0.24g silicon oil for all but Extra Lubricated which has 0.33g	0.49g silicon oil
Color	Transparent	None
Scent	Nivesse or none	None

Comparison of Modified Device with SLAM Predicate Device (K011253)

	SLAM Condom Manufactured by Nippon Rubber Industry; K011253	**Billy Boy with Dotted / Beaded Type**
FDA Classification	Class II § 884.5300	Class II § 884.5300
Classification code	HIS	HIS
Material	Natural latex rubber	Natural latex rubber
Shape	Anatomical Shape (i.e. narrowed along length)	Cylindrical Shape
Surface	Dotted (Beaded)	
Length	180 mm	≥ 175 mm
Flat Width (30 mm)	55 mm	52mm
max. width	55 mm	52 mm
narrowest flat width	55 mm	52 mm
thickness	0.10 mm	0.10 mm
	information at http://www.slamcondoms.com/v3/index.php?option=com_content&view=article&id=7&Itemid=8	

	Predicate Lifestyles Extra Strength Ultra Thick Male Latex Condom Manufactured by Ansell Inc. K871304	Submission Device BILLY BOY New Condom
FDA Classification	Class II § 884.5300	Class II § 884.5300
Classification code	HIS	HIS
Material	Natural latex rubber	Natural latex rubber
Shape	Cylindrical	Cylindrical
Length	200 mm	≥ 175 mm
Flat Width (30 mm)	55 mm	52 mm
max. width	55 mm	52 mm
narrowest flat width	55 mm	52 mm
thickness	0.10 mm	0.10 mm

information at
http://www.condomdepot.com/product/detail.cfm/nid/206/pid/2235

Comparison

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, thickness and width dimensions of the BillyBoy modifications are substantially equivalent to those of the other legally marketed predicate devices. Where differences exist, performance data has demonstrated that the differences do not raise any new issues of safety or efficacy.

Performance:

The materials testing for the BillyBoy was conducted in accordance with the relevant parts of ISO 10993. Certificates and test reports were provided demonstrating compliance with the standard. The sponsor followed FDA's guidance for male latex condoms and developed test plans to meet the specified requirements of the guidance. The functional testing of male condoms was conducted according to ASTM D3492. This testing included tensile force, elongation, tensile strength (both before and after aging) bursting volume, bursting pressure, freedom from holes and microbiological cleanliness using the ASTM standard acceptance criteria. In addition, the devices were evaluated for compliance with the standard with regard to length, wall thickness and visual characteristics. The BillyBoy condoms passed all materials, functional, and visual tests. In addition both accelerated and real time shelf life studies were performed with positive results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
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

JUN - 3 2011

Re: K111093
Trade Name: BillyBoy Dotted (Beaded) Condom; BillyBoy New Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product code: HIS
Dated: May 17, 2011
Received: May 20, 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

510(k) Number (if known): K111093

Device Name: BillyBoy Dotted (Beaded) Condom;
BillyBoy New Condom

Indications for Use:

Intended Use of the Device: The BillyBoy male latex condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections). The BillyBoy condoms are Dotted/Beaded and New Condom models.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111093