DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 7, 2017

Zhejiang Xiangban Latex Products Co., Ltd.
% Jonathan Hu
Technical Manager
Medwheat (Shanghai) Medical Technology Co., Ltd.
Yangpu District Liaoyuan East Road Shuangyang
First Suite No.33 Room 303
Shanghai 200093
China

Re: K162919
Trade/Device Name: Latex Condom for Men
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: January 18, 2017
Received: January 27, 2017

Dear Jonathan Hu:

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 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" (21 CFR 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 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,

Benjamin R. Fisher -S

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)*
K162919

Device Name
Latex Condom for Men

Indications for Use *(Describe)*
The Latex Condom for Men is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared: February 27, 2017

510(k) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	Zhejiang Xiangban Latex Products Co., Ltd.
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Contact Name:	Huichao Lou
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Email Address:	huichao679@sina.com

2. Correspondent's Information

Company Name:	Medwheat (Shanghai) Medical Technology Co., Ltd.
Address:	Yangpu District Liaoyuan East Road Shuangyang, First Suite No.33 Room 303, Shanghai, China 200093
Correspondent Name:	Jonathan Hu
Telephone No.:	86-021-65181421
Email Address:	Jonathan.hu@medwheat.com

3. Trade Name, Common Name, Classification

Trade Name:	Latex Condom for Men
Common Name:	Condom, Natural Rubber Latex
Mode Name:	Plain, Ribbed, Dotted
Classification Name:	Condom (21 CFR §884.5300)
Product Code:	HIS; condom
Classification Panel:	Obstetrics/Gynecology
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

The M. Dior Brand male latex condom cleared by FDA through 510(k) No.K083817 (Decision Date – September 16, 2009). The predicate device has not been subject to a design-related recall.

5. Description of the Device

The Latex Condom for Men is a single-use, non-sterile condom made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom is designed to conform to the standards including ASTM D3492 and ISO 4074. The condoms have either a smooth, dotted, or ribbed surface and have a straight walled nipple-end (SWNE) style within ASTM standard specifications D3492 Table 1 requirements, e.g., minimum length 160 mm, maximum width 54mm, and minimum thickness of 30μM. The device specifications are listed in the table below.

Parameter	Specification
Nominal length	180 ± 10 mm
Nominal width	52 ± 2 mm
Nominal thickness	0.06 - 0.07 mm
Primary package material	Aluminum film
Lubricant	Silicone oil
Dusting	Silicon dioxide

6. Intended Use/Indication for Use

The Latex Condom for Men is used for contraception and for prophylactic purpose (to help prevent pregnancy and the transmission of sexually transmitted diseases).

7. Technological Characteristics

The 510(k) subject condom products have the same technological characteristics as the predicate condom products. The design is in conformance with ASTM Latex Condom Standard D3492 and the condoms are made of natural rubber latex both are straight-walled, nipple-ended, lubricated condoms and made using the same basic formulations of compounded natural rubber latex.
A comparison of technological characteristics is provided in the following table. The differences in technology do not raise different questions of safety and effectiveness.

Technological Characteristics	Latex Condom for Men	M. Dior Brand (predicate device) - K083817
Intended Use	The Latex Condom for Men is used for contraception and for prophylactic purpose (to help prevent pregnancy and the transmission of sexually transmitted diseases).	The condom is used for contraception and for prophylactic purpose (to help prevent pregnancy and the transmission of sexually transmitted diseases).
Application	Single Use	Single Use
Material	Natural rubber latex	Natural rubber latex
Color	Natural	Natural
Nominal Length	180 ± 10 mm	160 mm
Nominal Width	52 ± 2 mm	54 mm
Nominal Thickness	0.06 - 0.07 mm	0.030 mm
Lubricant	Silicone oil	Unknown
Dusting	Silicon dioxide	Unknown
Packaging Material	Aluminum Film	Aluminum Film
Packaging Method	Heat-sealing	Heating-sealing
Biocompatibility	ISO10993 Acceptance criteria met	ISO10993 Acceptance criteria met

8. Discussion of Non-clinical Testing

The Latex Condom for Men from Zhejiang Xiangban Latex Products Co., Ltd. has been conducted related non-clinical tests to identify the substantial equivalence from the predicate device. The tests include the concerning of the biocompatibility, performance, and shelf-life, which contains the standards including ISO10993-5:2009 for determining cytotoxicity, ISO10993-10:2010 for determining sensitization, ISO10993-11:2006 for determining systemic toxicity, ASTM D3492-16 *Standard Specification for Rubber Contraceptives (Male Condoms)*, and ISO4074:2015 *Natural rubber latex condoms – Requirements and test methods*.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, it is concluded that the results of the testing described above demonstrate that the Latex Condom for Men is as safe and effective as the predicate device and support a determination of substantial equivalence.