August 5, 2022

Shanghai Personage Hygiene Products Co.,Ltd.
% Vincent Zhou
Regulatory Manager
Medwheat, Inc.
7900 International Drive, Suite 300
Bloomington, MN 55425

Re: K220576
Trade/Device Name: FAMA Male Latex Condoms
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: June 30, 2022
Received: July 6, 2022

Dear Vincent Zhou:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K220576

Device Name
FAMA Male Latex Condoms

Indications for Use *(Describe)*
The FAMA Male Latex Condoms are used for contraception and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary – K220576

## 1. Submitter Information

Applicant: Shanghai Personage Hygiene Products Co., Ltd.
Address: 88 Tianchen Road, Qingpu District,
Shanghai, 201700, China
Phone: 86-021-69214099
Email: haijiang_song@shbon.com

## 2. Correspondent Information

Contact: Vincent Zhou
Medwheat Inc.
Phone: 001-612-806-2995
Email: Info@medwheat.com

## 3. Date prepared: August 03, 2022

## 4. Device Information

| | |
|---|---|
| Device/Trade Name: | FAMA Male Latex Condoms |
| Common Name: | Male Natural Rubber Latex Condom |
| Regulation Number: | 21 CFR 884.5300 |
| Regulation Name: | Condom |
| Regulatory Class: | Class II |
| Product Code: | HIS (Condom) |

## 5. Predicate Device Information

| | |
|---|---|
| Device Name: | Male Latex Condoms |
| 510(k) Number: | K162919 |
| Manufacturer: | Zhejiang Xiangban Latex Products Co., Ltd. |
| Regulatory Class: | Class II |
| Product Code: | HIS (Condom) |

The predicate device has not been subject to a design-related recall.

## 6. Device Description

The FAMA Male Latex Condoms are single-use, non-sterile condoms made of a natural rubber latex sheath, which covers the penis with a closely fitted membrane. The condoms have a smooth, dotted or ribbed surface and have a straight-walled nipple-end (SWNE) style within specifications listed in ASTM D3492-16, *Standard Specification for Rubber Contraceptives (Male Condoms)*. The condoms are lubricated with no colorants and fragrances added. The product is made of natural rubber latex, additives are sulfur, zinc oxide, promoter PX, promoter ZDC, antioxidant 264, stabilizer casein, and silicone oil as lubricant. These condoms conform with FDA-recognized standards ASTM D3492-16 and ISO 4074:2015.

The device specifications are listed in the table below.

***Table 1: Condom specifications***

| Parameter | Specification |
|---|---|
| Nominal length | 180 ± 10 mm |
| Nominal width | 53 ± 2 mm |
| Nominal thickness | 0.046 – 0.047 mm (Plain)<br>0.068 – 0.069 mm (Dotted)<br>0.074 – 0.075 mm (Ribbed) |
| Burst pressure | ≥ 1.0 kPa |
| Burst volume | ≥ 18 $dm^3$ |
| Primary package material | Aluminum film |
| Lubricant | Silicone oil |
| Dusting | Silicon dioxide |

## 7. Indications for Use

The FAMA Male Latex Condoms are used for contraception and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

## 8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

***Table 1: Indications for Use and Technological Characteristics of the Subject Devices Compared to Predicate***

| | **Subject Device K220576** | **Predicate Device K162919** | **Comparison** |
|---|---|---|---|
| Trade Name | FAMA Male Latex Condoms | Male Latex Condom | N/A |
| Product Code | HIS | HIS | Same |
| Regulation Number | 21 CFR 884.5300 | 21 CFR 884.5300 | Same |
| Regulation Name | Condom | Condom | Same |
| Indications for Use | The FAMA Male Latex Condoms are used for contraception and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections). | The Latex Condom for Men is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases). | Same |
| Prescription or Over-The- Counter-Use | Over-The-Counter-Use | Over-The-Counter-Use | Same |

| | | | |
|---|---|---|---|
| Materials | Natural Rubber Latex | Natural Rubber Latex | Same |
| Lubricant Coating | Silicone | Silicone | Same |
| Design | Straight walled with nipple end; smooth, ribbed and dotted texture | Straight walled with nipple end; smooth, ribbed and dotted texture | Similar |
| Length | 180 ± 10 mm | 180 ± 10 mm | Same |
| Width | 53 ± 2 mm | 52 ± 2 mm | Different |
| Thickness | 0.046 – 0.047 mm (Plain)<br>0.068 – 0.069 mm (Dotted)<br>0.074 – 0.075 mm (Ribbed) | 0.06 - 0.07 mm | Different |
| Burst Pressure | ≥ 1.0 kPa | Not publicly available | N/A |
| Burst Volume | ≥ 18 $dm^3$ | Not publicly available | N/A |
| Sterilization | Non-sterile | Non-sterile | Same |
| Shelf Life | 5 years | 3 years | Different |

The subject and predicate devices have similar indications for use and have the same intended use. The subject device has the same basic technological characteristics of the predicate such as the base material (NRL), shape, texture and silicone lubricant. The differences in technological characteristics (dimensions, shelf-life, minor variation in composition) do not raise different questions of safety and effectiveness.

**9. Summary of Non-Clinical Performance Testing**

**Biocompatibility**

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization testing were performed in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009/R 2014)
- Sensitization (ISO 10993-10:2010/R 2014)
- Vaginal Irritation (ISO 10993-10:2010/R 2014)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrated that the subject devices are non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

**Physical Testing**

The FAMA Male Latex Condoms were tested at baseline and met all the requirements of ISO 4074:2015 - *Natural rubber latex male condoms – Requirements and test method*s and ASTM D3492-16 - *Standard Specification for Rubber Contraceptives (Male Condoms).*

**Shelf-Life**

The FAMA Male Latex Condoms have a five-year shelf life based on the results of accelerated stability

evaluations conducted as required in 21 CFR 801.435. All samples met predefined acceptance criteria.

**10. Conclusion**

The results of the performance testing described above demonstrate that the FAMA Male Latex Condoms are as safe and effective as the predicate device and supports a determination of substantial equivalence.