



September 21, 2026

Shanghai Personage Hygiene Products Co., Ltd.
% Vincent Zhou
Regulatory Affairs Manager
Medwheat, Inc.
7900 International Dr. #300
Bloomington, Minnesota 55425

Re: K262108
Trade/Device Name: FAMA/MO/Mingliu Male Natural Rubber Latex Condoms –
Aqueous Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: June 23, 2026
Received: June 23, 2026

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 (the 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 available 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: The Center for Devices and Radiological Health (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, The Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

510(k) Number (if known)

K262108

Device Name

FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant

Indications for Use (Describe)

The FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant are used for contraception and prophylactic purposes (to help prevent pregnancy and 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.

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510(k) Summary – K262108

[As required by 21 CFR 807.92]

1. Submitter Information

Name of Sponsor: Shanghai Personage Hygiene Products Co., Ltd.
Address: 88 Tianchen Road, Qingpu District, Shanghai,
201700, China
Contact Name: Zhengjun Zhu
Telephone No.: 86-021-69214099
Fax No.: 86-021-69214100
Email Address: information@shbon.com
Date Prepared: September 18, 2026

2. Correspondent Information

Company Name: Medwheat Inc.
Correspondent Name: Vincent Zhou
Telephone No.: 001-612-806-2995
Email Address: us.agent@medwheat.com

3. Device Information

Device Trade Name: FAMA/MO/Mingliu Male Natural Rubber Latex
Condoms – Aqueous Lubricant
Common Name: Natural rubber latex male condoms
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: HIS (Condom)
Device Class: II

4. Identification of Predicate Device

K220576: FAMA Male Latex Condoms

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

5. Description of the Device

FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant are single-use, non-sterile male condoms. Each condom consists of a natural rubber latex sheath designed to form a closely fitted membrane over the penis. Available with smooth, dotted, or ribbed surfaces, the condoms feature straight-walled or contoured profiles with nipple-ended geometry. The product line is engineered and manufactured to conform fully with international and national performance standards, including ISO 4074:2015 and ASTM D3492-16.

Parameter	Specification
Nominal length	185 ± 10 mm
Nominal width	49 ± 2 mm (Ultra-thin) 53 ± 2 mm (Ultra-thin; Plain; Dotted; Ribbed; Non-regular Shaped) 56 ± 2 mm (Ultra-thin; Plain; Non-regular Shaped)
Nominal thickness	0.045 - 0.055 mm (Ultra-thin) 0.055 – 0.075 mm (Plain) 0.060 – 0.080 mm (Dotted) 0.055 – 0.075 mm (Ribbed) 0.060 – 0.085 mm (Non-regular Shaped)
Primary package material	Blister Packaging (Polypropylene (PP) base tray with an aluminium film sealing lid)
Lubricant	Aqueous - 1600±100mg / 1200±100mg (HA+) - 800±100mg (HA)
Dusting	Silicon dioxide

6. Indications for Use

The FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant are used for contraception and prophylactic purposes (to help prevent pregnancy and sexually transmitted infections).

7. Comparison of Intended Use and Technological Characteristics

The table below compares the intended use and technological characteristics of the subject device and predicate device.

510(k) Submission

Technical Characteristics	FAMA/MO/Mingliu Male Natural Rubber Latex Condom – Aqueous Lubricant		FAMA Male Latex Condom – Silicone Oil (predicate device) – K220576	
Intended Use	The FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant are used for contraception and prophylactic purposes (to help prevent pregnancy and sexually transmitted diseases).		The FAMA Male Latex Condoms are used for contraception and prophylactic purposes (to help prevent pregnancy and sexually transmitted diseases).	
Application	Single use		Single use	
Material	Natural rubber latex		Natural rubber latex	
Color	Natural		Natural	
Nominal Length	185 ± 10 mm		180 ± 10 mm	
Nominal Width	49 ± 2 mm	Ultra-thin	53 ± 2 mm	Plain; Dotted; Ribbed;
	53 ± 2 mm	Ultral-thin; Plain; Dotted; Ribbed; Non-regular Shaped		
	56 ± 2 mm	Ultral Thin; Plain; Non-regular Shaped		
Nominal Thickness	0.045-0.055 mm	Ultral Thin		
	0.055-0.075 mm	Plain	0.046-0.047 mm	Plain
	0.060-0.080 mm	Dotted	0.068-0.069 mm	Dotted
	0.055-0.075 mm	Ribbed	0.074-0.075 mm	Ribbed
	0.055-0.085 mm	Non-regular Shaped		
Lubricant	Aqueous		Silicone oil	
	1600±100mg / 1200±100mg (HA+)	800±100mg (HA)	300 – 600 mg	
Dusting	Silicon dioxide		Silicon dioxide	
Packaging Material	Blister Packaging (PP base with Aluminum Film Lidding)		Aluminum Film	
Packaging Method	Heat-sealing		Heat-sealing	
Shelf Life	Five years		Five years	

The subject and predicate device have the same intended use – for contraception and prophylactic purposes. The subject device has the same basic technological characteristics of the predicate device, such as the base material (NRL), texture, length, shelf life and packaging. The difference in technological characteristics (dimensions, lubricant, shape) do not raise different questions of safety and effectiveness. The differences can be evaluated through performance testing.

8. Summary of Non-Clinical Performance Testing

Performance Testing

FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant from Shanghai Personage Hygiene Products Co., Ltd. was tested and met the requirements of ASTM D3492-16 *Standard Specification for Rubber Contraceptives (Male Condoms)* and ISO 4074:2015 *Natural Rubber Latex Condoms – Requirements and test methods*.

Shelf-Life

FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant has 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.

Biocompatibility

Biocompatibility evaluations were performed on the FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant in accordance with the 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” dated September 2023. The biocompatibility evaluations conducted, and the applicable ISO standards are listed below:

- Cytotoxicity (ISO10993-5:2009)
- Sensitization (ISO10993-10:2021)
- Vaginal irritation (ISO10993-23:2021)
- Acute systemic toxicity (ISO10993-11:2017)

The results of testing demonstrate that the subject device is non-cytotoxic, non sensitizing, non-irritating, and not acutely systemically toxic.

10. Conclusion

The results of performance testing above demonstrates that FAMA/MO/Mingliu Male Natural Rubber Latex Condoms – Aqueous Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.