December 6, 2017

Wettrust Korea Co., Ltd.
% Jigar Shah
Consultant
mdi Consultants, Inc.
55 Northern Blvd.
Great Neck, NY 11021

Re: K170797
Trade/Device Name: wettrust D2care
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 24, 2017
Received: October 26, 2017

Dear Jigar Shah:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For 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)*
K170797

Device Name
wettrust D2care

Indications for Use *(Describe)*
wettrust D2care is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex or polyurethane condoms. This product is compatible with synthetic polyisoprene condoms.

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.

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"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

Date Prepared: December 5, 2017

1. Company and Correspondent:

	Company
Name	Wettrust Korea Co., Ltd.
Address	312 The Prau, 27 Jeongjail-ro, Bundang-gu Seongnam, Gyeonggi-do, Korea 463-480
Phone Fax Contact	+82(31) 719-8394 +82(31) 719-8395 Sungho Lee / Director

2. Device:

Proprietary Name	wettrustD2care
Common Name	Personal Lubricant
Classification Name	Condom (21 CFR 884.5300)
Product code	NUC (lubricant, personal)
Class	II

3. Predicate Device:
   Replens Long-lasting Vaginal Moisturizer (K101241)
   The predicate device has not been subject to a design-related recall.

4. Description:
   wettrust D2care is a water-based personal lubricant that is packaged in a single use pre-filled one-push syringe. The primary ingredients include water, glycerin, and hydroxethylcellulose. The device specifications include appearance, color, odor, pH, viscosity, osmolality, antimicrobial effectiveness, total aerobic microbial count, total yeast and mold count, and absence of pathogenic organisms.

5. Indications for use:
   wettrust D2care is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex or polyurethane condoms. This product is compatible with synthetic polyisoprene condoms.

6. Substantial Equivalence Discussion

The following tables outline the similarities and differences between wettrust D2care and the predicate device.

Device Name	WettrustD2care (Subject Device)	Replens Long-lasting Vaginal Moisturizer (Predicate Device)
510(k)	K170797	K101241
Manufacturer	Wettrust Korea Co., Ltd.	Lil Drug Store Products, Inc.
Indications for Use statement	wettrust D2Care is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This product is not compatible with natural rubber latex or polyurethane condoms. This product is compatible with synthetic polyisoprene condoms.	Replens is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms.
Ingredients	Purified water Glycerin Hydroxyethylcellulose Sodium Lactate Methylparaben Aloe Barbadensis Leaf Juice Butylene glycol Camellia Sinensis Leaf Extract Lactic acid Chamomilla Recutita (Matricaria) Flower Extract Morus Alba Bark Extract Disodium EDTA SodiumHyaluronate	Purified water Glycerin Mineral Oil Polycarbophil Carbomer Homoploymer Type B Sorbic Acid Sodium Hydroxide. Methylparaben Hydrogenated Palm Oil Glyceride

Condom Compatibility	Synthetic polyisoprene condoms	Natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms
Sterilization	Non-sterile	Non-sterile
Single Use Applicator	Yes	Yes

The subject and predicate device have the same intended use – supplementation of lubrication during intercourse.

The subject and predicate device have different technological characteristics, including ingredients and specifications. These differences in technological characteristics do not raise different questions of safety and effectiveness.

7. Non-Clinical Performance Data

The following tests were completed on wettrust D2care in accordance with national and international standards to support substantial equivalence to the predicate device.

- Biocompatibility (per ISO 10993-1), including cytotoxicity, sensitization, irritation, and acute systemic toxicity, demonstrating that the subject device is biocompatible
- Condom Compatibility Testing (per ASTM D7661) demonstrating that the subject device is compatible with synthetic polyisoprene condom
- Antimicrobial Effectiveness Testing (per USP <51>)
- Total Aerobic Microbial Counts (per USP <61>)
- Total Combined Yeast and Mold Counts (per USP <61>
- Absence of Pathogenic Organisms (per USP <62>)
- Shelf Life (per ASTM F1980) demonstrating that the subject device meets its specifications over the duration of its proposed shelf life

8. Conclusion

The wettrust D2care is substantially equivalent to the proposed predicate device.