December 6, 2024

Project Chemistry, Inc.
℅ Louie Goryoka
Sr. Consultant RA/QA
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K242645
Trade/Device Name: INA Moisturizing Intimate Water-Based Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 4, 2024
Received: September 9, 2024

Dear Louie Goryoka:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Michael T. Bailey -S

For
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)*
K242645

Device Name
INA Moisturizing Intimate Water-Based Personal Lubricant

Indications for Use *(Describe)*
INA Moisturizing Intimate Water-Based Personal Lubricant is a personal lubricant, for penile and/or 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, polyurethane, and 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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510(K) SUMMARY

Submitter Information

A. Company Name: Project Chemistry

B. Company Address: 18241 Gothard St.
Huntington Beach, CA 92648

C. Company Phone: (714) 587-9011

D. Company Contact Jessica Graham – Sr. Director, Product Development

E. Submission Correspondent: Louie Goryoka
Sr. VP. Regulatory and Quality Consultant
Med-Device Consulting, Inc.
Email: mdci@m-dci.us
(818) 585-7488

F. Summary Preparation Date: December 4, 2024

Device Identification

A. Device Trade Name: INA Moisturizing Intimate Water-Based Personal Lubricant
B. Common Name: Personal Lubricant

C. Regulation Name: Condom

D. Regulation Number: 21 CFR §884.5300

E. Device Class: Class II

F. Product Code: NUC (lubricant, personal)

H. Predicate Devices The Sex Gel Personal Lubricant, K181078.

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

Indications for Use Statement

INA Moisturizing Intimate Water-Based Personal Lubricant is a personal lubricant, for penile and/or 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, polyurethane, and polyisoprene condoms.

Device Description

INA Moisturizing Intimate Lubricant Water-Based Personal Lubricant is a non-sterile, water-based, personal lubricant that is compatible with natural rubber latex, polyisoprene, and polyurethane

condoms. The device is for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity supplement the body's natural lubrication.

INA Moisturizing Intimate Lubricant Water-Based Personal Lubricant is sold as an over-the-counter (OTC) product in a 3 fl. oz./ 90 mL Polyethylene and Ethylene vinyl alcohol bottle with Polypropylene flip cap. The Tube will be packaged in an outer box.

This product is composed of Deionized Water, Organic Certified Aloe Vera Gel, Madecassoside, Asiaticoside, Centella Asiatica Leaf Extract, Propanediol, Sclerotium Gum, Sodium Hyaluronate, Tremella Fuciformis Sporocarp Extract, Xanthan Gum, Lactic Acid, Red Alga Gel EC, Sodium Benzoate, Potassium Sorbate, Moringa Oleifera Seed Oil, Cariborg Sea Buckthorn Oil Refined.

The device specifications are listed in the table below:

Table 1: Device Specifications for INA Moisturizing Intimate Water-Based Personal Lubricant

Property	Specification
Appearance	Translucent Viscous Gel
Color	Straw
Odor	None
Viscosity	8,000 - 10-400 cps
pH	4.3 - 5.3
Osmolality (mOSm/kg)	1394 - 1428 mOSm/kg
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<100 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2 bacteria should show a log reduction of less than 2.0 at 14 days and no increase from the 14-day count to the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days
Presence of Pathogens per USP <62>	**Specification**
Absence of pathogenic organisms (*Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, E. coli*, coliforms, *Salmonella*, and enrichment pathogens*)* per USP <62>	Absent

Comparison of Intended Use and Technological Characteristics with Predicate Device:

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

Characteristic/Feature	**INA Moisturizing Intimate Lubricant Water-Based Personal Lubricant Subject Device (K242645)**	**The Sex Gel Water-Based Personal Lubricant Predicate Device (K181078)**
Indications for Use	INA Moisturizing Intimate Water-Based Personal Lubricant is a personal lubricant, for penile and/or 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, polyurethane, and polyisoprene condoms.	The Sex Gel is a personal lubricant, for penile and/or 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 latex, polyisoprene, and polyurethane condoms.
Water-Based Lubricant	**Yes**	**Yes**
Over the Counter	**Yes**	**Yes**
Non-sterile	**Yes**	**Yes**
Odor	Odorless	Characteristic
Viscosity	8,000 cps – 10,400 cps	3,000 cps – 5,000 cps
pH	4.3 -5.3	4.0 – 5.0
Osmolality	1394 – 1428 mOSm/kg	435-535 mOsm/kg
Microbial Limits	Total mold/yeast count <10 cfu/g Total aerobic microbial count <100 cfu/g Absence of pathogenic organisms	Total mold/yeast count <10 cfu/g Total aerobic microbial count <10 cfu/g Absence of pathogenic organisms
Antimicrobial Effectiveness Testing (USP<51> Category 2)	**Yes**	**Yes**
Condom Compatibility	Compatible with natural latex, polyisoprene, and polyurethane condoms.	Compatible with natural latex, polyisoprene, and polyurethane condoms.

Primary ingredients	Deionized Water, Organic Certified Aloe Vera Gel, Madecassoside, Asiaticoside, Centella Asiatica Leaf Extract, Propanediol, Sclerotium Gum, Sodium Hyaluronate, Tremella Fuciformis Sporocarp Extract, Xanthan Gum, Lactic Acid, Red Alga Gel EC, Sodium Benzoate, Potassium Sorbate, Moringa Oleifera Seed Oil, Cariborg Sea Buckthorn Oil Refined.	Water, aloe barbadensis leaf juice, sorbitol, hydroxyethylcellulose, allantoin, lactic acid/tocopherols (vitamin E), sodium hyaluronate, sodium benzoate & potassium sorbate
Sterile	No	No
Shelf life	6 months	6 months

The subject and predicate device have similar indications for use and have the same intended use (i.e., provides lubrication during intimate sexual activity). The subject and predicate device have different technological characteristics, including variations in formulations and specifications (e.g., pH, osmolality, etc.). The differences in the technological characteristics of the subject and predicate do not raise different questions of safety and effectiveness.

Performance Data

Biocompatibility

Biocompatibility testing on the subject lubricant was performed in accordance with the 2023 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", as follows:

- Cytotoxicity (ISO 10993-5:2009/(R)2014)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2021)
- Vaginal Irritation (ISO 10993-23: 2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

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

Condom Compatibility

Condom compatibility studies were performed per ASTM-D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" on INA Moisturizing Intimate Lubricant Water-Based Personal Lubricant and was determined to be compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Shelf Life Testing

The INA Moisturizing Intimate Lubricant Water-Based Personal Lubricant is shown to have a 6 month shelf life utilizing real time aging. Testing on samples showed that the subject device met all device specifications listed in Table 1 above across the device shelf-life.

Conclusion

The results of the performance testing described above demonstrate that the INA Moisturizing Intimate Lubricant Water-Based Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.