November 18, 2021

Good Clean Love, Inc.
% Abhishek K. Gurnani
Partner
Amin Talati Wasserman, LLP
100 S. Wacker Drive Suite 2000
Chicago, IL 60606

Re: K212000
Trade/Device Name: Medley
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 14, 2021
Received: October 19, 2021

Dear Abhishek K. Gurnani:

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,

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)*
K212000

Device Name
Medley

Indications for Use *(Describe)*
Medley 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 and polyisoprene condoms. This product is not compatible with polyurethane 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.***

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**
**K212000**
**Medley**

**Submitter:** Good Clean Love, Inc.
207 West 5th Avenue
Eugene, OR 97401
Contact: Wendy Strgar
Phone: 541 344 4483
Email: Wendy@GoodCleanLove.com

**Contact Person:** Abhishek K. Gurnani
Amin Talati Wasserman, LLP
100 South Wacker Drive, Suite 2000
Chicago, IL 60606
Phone: 312 327 3325
Fax: 312 884 7352
Email: Abhishek@AminTalati.com

**Summary Prepared:** November 16, 2021

**Trade Name:** Medley
**Common Name:** Personal Lubricant
**Regulation Number:** 21 CFR 884.5300
**Regulation Name:** Condom
**Regulatory Class:** Class II
**Product Code:** NUC (lubricant, personal)

**Predicate Device:** K191480, WET Water Based Personal Lubricant (additionally branded as WET Platinum Houston, Elite Water-Based Hybrid) Trigg Laboratories, Inc, D/B/A Wet International

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

**Device Description**: Medley is a water-based personal lubricant that is non-sterile and provides lubrication during intimate sexual activity. This device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms. Its formulation consists of water, hydroxyethylcellulose, xanthan gum, hyaluronic acid, Zemea propanediol, glycerin water, dimethicone, hydrogenated lecithin, sodium benzoate, potassium sorbate, and DL lactic acid. Medley is packaged in 2 fl. oz high-density polyethylene pump bottles. Medley is a personal lubricant for over-the-counter (OTC) use.

Device specifications are listed in Table 1 below.

***Table 1: Subject Device Specifications***

| **Property** | **Specifications** |
|---|---|
| Appearance | Gel |
| Color | Colorless to Slightly Yellow and Cloudy |
| Odor | Characteristic |
| Viscosity | 12,500 – 25,000 cps |
| Osmolality | 250 – 400 mOsm/kg |
| pH | 3.5-4.0 |
| Total Aerobic Microbial Count (TAMC, per USP <61>) | <100 cfu/g |
| Total Yeast & Mold Count (TYMC, per USP <61>) | <10 cfu/g |
| **Presence of Pathogens per USP <62>** | **Specification** |
| *Pseudomonas aeruginosa* | Absent |
| *Staphylococcus aureus* | Absent |
| *Salmonella* | Absent |
| *Escherichia coli* | Absent |
| *Clostridium Species* | Absent |
| *Candida albicans* | Absent |
| **Antimicrobial Effectiveness Testing (per USP <51>** | **Specification** |
| Bacteria | Meets USP <51> criteria for category 2. No less than 2.0 log reduction from initial count at 14 days, and no increase from the 14-day count at 28 days |
| Yeast and molds | No increase from the initial calculated count at 14 and 28 days |

**Indications for Use Statement:** Medley 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

**Comparison of Intended Use and Technological Characteristics:**

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

**Table 2. Intended Use and Technological Characteristics of Medley as Compared to the Predicate**

| | Subject Device (K212000) | Predicate (K191480) |
|---|---|---|
| Sponsor | Medley | WET Water Based Personal Lubricant (additionally branded as WET Platinum Houston, Elite Water-Based Hybrid) |
| Regulation Number<br>Product Code<br>Device Class | 844.5300<br>NUC<br>II | 844.5300<br>NUC<br>II |
| Indications for Use | Medley 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms. | The Wet Water Based Personal Lubricant (additionally, branded as WET Platinum Houston, Elite Water-Based Hybrid) is a personal lubricant for penile, anal 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Rx/OTC | OTC | OTC |
| Water-based | Yes | Yes |
| Ingredients | Water<br>Hydroxyethylcellulose<br>Xanthan Gum<br>Hyaluronic Acid<br>Zemea Propanediol<br>Glycerin Water<br>Dimethicone<br>Hydrogenated Lecithin<br>Sodium Benzoate<br>Potassium Sorbate | Propylene Glycol<br>Water<br>Dimethicone<br>Cyclopentasiloxane<br>PEG/PPG 18/18 Dimethicone<br>Caprylhydroxamic Acid<br>1,2-Hexanediol<br>Propanediol<br>Sodium Polyacrylate<br>Trideceth-6<br>Hydroxyethylcellulose<br>Sodium Acetate |

| | DL Lactic Acid | Cellulose |
|---|---|---|
| Sterile | No | No |
| Appearance/Color | Gel, Colorless to Slightly Yellow and Cloudy | Slightly Cloudy |
| Odor | Characteristic | Odorless |
| Viscosity | 12,500-25,000 cps | 5,000-13,000 cps |
| pH | 3.5-4.0 | 6.0-7.5 |
| Osmolality | 250-400 mOsm.kg | 3,691-6,140 mOsm/kg |
| Total Aerobic Microbial Count (TAMC) | <100 cfu/g | <10 cfu/g |
| Total Yeast and Mold Count (TYMC) | <10 cfu/g | <10 cfu/g |
| Absence of Pathogenic Organisms | Absent | Absent |
| Condom Compatibility | Natural Rubber Latex and Polyisoprene | Natural Rubber Latex and Polyisoprene |
| Shelf life | 1 year | 1.5 years |
| Biocompatibility Tested | Yes | Yes |
| Antimicrobial Effectiveness Tested | Yes | Yes |

The subject and predicate devices have differences in their indications for use (IFU) statements. Both have the same intended use for lubrication during intimate sexual activity and have the same compatibility with condoms. However, the predicate is also indicated for anal use, while the subject device is not. This difference does not represent a new intended use, but rather a more limited use for the subject device.

As shown in the table above, the subject and predicate device have different technological characteristics, including formulation, appearance, odor, viscosity, pH, osmolality, TAMC, and shelf-life duration. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

**Summary of Performance Data:**

**Biocompatibility:** Biocompatibility studies 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." The following testing was conducted:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization and irritation testing using the human repeat insult patch test, an alternative test method to ISO 10993-10:2010
- Acute systemic toxicity testing per ISO 10993-11:2017

The results of testing demonstrate that Medley is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

**Condom Compatibility:** The compatibility of the subject device with condoms was evaluated in accordance with ASTM D7661-8 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" and was determined to be compatible with natural rubber latex and polyisoprene condoms. The subject device was determined not to be compatible with polyurethane condoms.

**Shelf Life:** Medley has a one-year shelf-life. Results from an accelerated aging study demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

**Conclusion:** The results of the performance testing described above demonstrate that Medley is as safe and effective as the predicate device and supports a determination of substantial equivalence.