



November 18, 2021

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

Re: K211998
Trade/Device Name: Desnuda Reflect
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 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

Indications for Use

510(k) Number (if known)

K211998

Device Name

Desnuda Reflect

Indications for Use (Describe)

Desnuda Reflect 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.

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510(k) Summary
K211998
Desnuda Reflect

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

Predicate Device: K150883, HyaloGYN[®] Vaginal Hydrating Gel
Fidia Farmaceutici, S.p.A.

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

Device Description: Desnuda Reflect 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, hydroxyethyl cellulose, xanthan gum, hyaluronic acid, Zemea propanediol, sodium benzoate, potassium sorbate, and DL lactic acid. Desnuda Reflect is packaged in 2 fl. oz high-density polyethylene pump bottles. Desnuda Reflect is a personal lubricant for over-the-counter (OTC) use.

Device specifications are listed in Table 1 below.

Table 1: Device Specifications for Desnuda Reflect

Property	Specifications
Appearance	Gel
Color	Clear to 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
<i>Pseudomonas aeruginosa</i>	Absent
<i>Staphylococcus aureus</i>	Absent
<i>Salmonella</i>	Absent
<i>Escherichia coli</i>	Absent
<i>Clostridium Species</i>	Absent
<i>Candida albicans</i>	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: Desnuda Reflect 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 Desnuda Reflect as Compared to the Predicate

	Subject Device (K211998)	Predicate (K150883)
Sponsor	Desnuda Reflect	HyalogYN [®] Vaginal Hydrating Gel
Regulation Number Product Code Device Class	844.5300 NUC II	844.5300 NUC II
Indications for Use	Desnuda Reflect 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.	HyalogYN [®] 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 polyisoprene condoms.
Rx/OTC	OTC	OTC
Water-based	Yes	Yes
Ingredients	Water Hyaluronic Acid Hydroxyethylcellulose Xanthan Gum Zemea Propanediol Sodium Benzoate Potassium Sorbate DL Lactic Acid	Water Hyaluronic Acid Propylene Glycol Carbomer Preservatives Sodium Hydroxide
Sterile	No	No
Applicator	No	Yes
Condom Compatibility	Natural Rubber Latex and Polyisoprene Condoms	Polyisoprene Condoms

Shelf life	1 year	3 years
Biocompatibility Tested	Yes	Yes
Microbiology Tested (absence of pathogenic organisms, TAMC, and TYMC)	Yes	Yes
Osmolality Tested	Yes	Yes
pH Tested	Yes	Yes
Physical Characteristics Tested (appearance, color, and odor)	Yes	Yes
Antimicrobial Tested	Yes	Yes

The subject and predicate device have similar indications for use, and the intended use of the subject and predicate device is the same, i.e., provides lubrication during intimate sexual activity. As noted in the table above, the subject and predicate device have different technological characteristics, including formulations, condom compatibility, use of an applicator, and shelf-life. 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 Desnuda Reflect 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 D7661-18 “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: Desnuda Reflect 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 Desnuda Reflect is as safe and effective as the predicate device and supports a determination of substantial equivalence.