November 7, 2019

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

Re: K190872
Trade/Device Name: BioGenesis Fertility Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB
Dated: October 7, 2019
Received: October 8, 2019

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,

Monica D. Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190872

Device Name
BioGenesis Fertility Lubricant

Indications for Use *(Describe)*
BioGenesis Fertility 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. BioGenesis Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. BioGenesis Fertility Lubricant is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

BioGenesis Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.

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 – K190872

This summary uses the format provided in 21 CFR 807.92:

(1) **Submitter/Owner:**

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Summary Prepared: November 7, 2019

(2) **Trade Name:** BioGenesis Fertility Lubricant

Common Name: Personal Lubricant

Regulation Number: 21 CFR 884.5300

Regulation Name: Condom

Regulatory Class: Class II

Product Code: PEB (lubricant, personal, gamete, fertilization, and embryo compatible)

(3) **Identification of Predicate Device:** BabyDance Fertility Lubricant (K162319)

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

(4) **Device Description:** BioGenesis Fertility Lubricant is water-based formula with ingredients including lactic acid, hydroxyethylcellulose, sodium chloride, potassium sorbate, sodium benzoate, potassium chloride, sorbic acid, magnesium chloride, and calcium chloride. The product is provided in a tube container and has a gel consistency. Its specifications are listed in Table 1 below. The lubricant is not a spermicide or contraceptive. It is compatible with natural rubber latex and polyisoprene condoms. It is

not compatible with polyurethane condoms. It is also compatible with compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples.

Table 1: Subject Device Specifications

Property	Specification
Appearance	Gel
Color	Clear
Odor	Characteristic
Viscosity	1,200-10,000 cps
Osmolality	300–400 mOsm/kg
pH at 25 °C	3.8-4.2
Endotoxin	< 0.5 EU/mL
Human Sperm Survival	≥ 70% after 24 hours
Total Aerobic Microbial Count (USP <61>)	<100 cfu/g
Total Yeast & Mold Count (USP <61>)	<10 cfu/g
Absence of Pathogenic Organisms (USP <62>)	
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Escherichia coli, Salmonella, Clostridium Species	Absent
Antimicrobial Effectiveness (USP<51>)	
Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus	NLT a 2.0 log reduction from initial count at 14 days and no increase from the 14-day count at 28 days
Candida albicans, Aspergillus niger	No increase from the initial calculated count at 14 and 28 days

(5) **Indications for Use Statement:** BioGenesis Fertility 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. BioGenesis Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. BioGenesis Fertility Lubricant is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

BioGenesis Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.

(6) **Substantial Equivalence Discussion**

The table below compares the intended use and technological characteristics of the subject and predicate devices:

Table 2. Technological Characteristics of BioGenesis Fertility Lubricant as Compared to the Predicate Device

	BioGenesis Fertility Lubricant K190872	BabyDance Fertility Lubricant K162319
	Subject Device	**Predicate Device**
Sponsor	Good Clean Love Inc.	Fairhaven Health, LLC
Indications for Use	BioGenesis Fertility 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. BioGenesis Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. BioGenesis Fertility Lubricant is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms. BioGenesis Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.	BabyDance Fertility 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. BabyDance Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. BabyDance Fertility Lubricant is compatible with natural rubber latex and polyurethane condoms. BabyDance Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.
Regulation Number	884.5300	884.5300

Product Code Device Class	PEB II	PEB II
Base Type	Water	Water
Primary Ingredients	Water Hydroxyethylcellulose Sodium Chloride Potassium Chloride Calcium Chloride Magnesium Chloride Potassium Benzoate Sodium Benzoate Sorbic Acid Lactic Acid	Water Cetyl Hydroxyethylcellulose Hypromellose Carbomer Homopolymer Monobasic Sodium Phosphate Dibasic Potassium Phosphate Sodium Chloride D-Xylose Sodium Hydroxide Phenethyl Alcohol Caprylyl Glycol Salvia Sclarea
Over the Counter Use	Yes	Yes
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Condom Compatibility	Natural Rubber Latex Polyisoprene	Natural Rubber Latex Polyurethane
Shelf-Life	12 Months	9 Months

The subject and predicate devices have the same indications for use statements and have the same intended use. As noted in the table above, the subject and predicate device have different technological characteristics, including a different formulation and a different shelf life. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

(7) **Summary of Performance Data:**

As part of demonstrating substantial equivalence to the predicate device, the following non-clinical performance tests were conducted.

- **Biocompatibility.** BioGenesis Fertility Lubricant has undergone biocompatibility testing including cytotoxicity per ISO 10993-5:2009, human repeat insult patch testing (sensitization and irritation), and acute systemic toxicity testing per ISO 10993-11:2006. The testing found that BioGenesis Fertility Lubricant is biocompatible.

- **Non-clinical Performance Testing.** Human sperm survival assay (HSSA), and lubricant barrier assay testing was conducted and indicates that BioGenesis Fertility Lubricant is compatible with sperm and does not inhibit sperm motility.

- **Condom Compatibility.** BioGenesis Fertility Lubricant was tested for condom compatibility per ASTM D7661-10: *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results of this test indicate that BioGenesis Fertility Lubricant is compatible with natural rubber latex and polyisoprene condoms. BioGenesis Fertility Lubricant is not compatible with polyurethane condoms.

- **Shelf Life.** The results of accelerated aging shelf-life testing demonstrated that BioGenesis Fertility Lubricant maintains its specifications over the duration of its proposed shelf life of twelve months.

(8) **Conclusion**

The results of performance testing described above demonstrate that the BioGenesis Fertility Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.