DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 28, 2017

Fairhaven Health, LLC
Suzanne Munson
VP of Product Development/Compliance
1410 11th Street
Bellingham, WA 98225

Re: K162319
Trade/Device Name: BabyDance Fertility Lubricant™
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB
Dated: March 30, 2017
Received: March 31, 2017

Dear Suzanne Munson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

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)*
K162319

Device Name
BabyDance Fertility Lubricant™

Indications for Use *(Describe)*

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.

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

I. General Information on Submitter

Address: Fairhaven Health, LLC
1410 11th Street
Bellingham, WA 98225

Telephone: 360-543-7888
Email: suzanne@fairhavenhealth.com
Contact Person: Suzanne Munson
Date Prepared: April 27, 2017

II. General Information on Device

Proprietary Name: BabyDance Fertility Lubricant™
Common Name: Personal Lubricant
Classification Name: Condom (21 CFR 884.5300)
Product Code: PEB (Lubricant, Personal, Gamete, Fertilization, and Embryo Compatible
510(k) Number: K162319

III. Predicate Device

Pre-Va Vaginal Lubricant (K072741), manufactured by INGFertility, LLC. This predicate device has not been subject to any design related recalls.

IV. Description of Device

This device is a non-sterile, water-based personal lubricant for vaginal and/or penile application. The formulation does not harm sperm function and has a pH and osmolality that are physiologic ("balanced") to that of fertile cervical mucus and semen. The device is compatible with latex and polyurethane condoms.

BabyDance Fertility Lubricant™ is formulated using purified water, cetyl hydroxyethylcellulose, hypromellose, carbomer homopolymer type B, sodium phosphate, potassium phosphate, sodium chloride, xylose, sodium hydroxide, phenethyl alcohol, caprylyl glycol, and Salvia sclarea. This device is supplied with an applicator.

The device specifications for the BabyDance Fertility Lubricant™ include appearance, odor, pH, viscosity, osmolality, total aerobic microbial count, total yeast and mold count, absence of pathogenic organisms (*Escherichia coli, Staphylococcus. aureus, Salmonella, Pseudomonas aeruginosa,* and *Candida albicans*), endotoxin, mouse

embryo assay (MEA), and human sperm survival assay (HSSA). These specifications were evaluated during the length of the proposed shelf-life and will be tested before lot release.

V. Indications for Use

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.

VI. Technological Characteristics of Device Compared to Predicate Device

Attribute	BabyDance Fertility Lubricant	Pre~Va Vaginal Lubricant
Base of product	Water	Water
Condom Compatibility	Compatible with latex and Polyurethane condoms	Compatible with latex and Polyurethane condoms
Ingredients	Purified water, cetyl hydroxyethylcellulose, hypromellose, carbomer homopolymer type B, sodium phosphate, potassium phosphate, sodium chloride, xylose, sodium hydroxide, phenethyl alcohol, caprylyl glycol, Salvia sclarea	Water, Hydroxyethylcellulose, Pluronic 127, Sodium Chloride, Arabinogalactan, Sodium Phosphate, Carbopol 934P, Methyl Paraben, Sodium Hydroxide, Potassium Phosphate

Both the subject and predicate devices are water-based personal lubricants and have the same condom compatibility. They have different formulations and different values for their specifications; however, these differences do not raise different questions of safety and effectiveness.

VII. Summary of Non-clinical Performance Testing

The following studies have been performed to ensure safety and effectiveness of subject device:

- Physical testing (appearance, pH, viscosity and osmolality) on freshly manufactured and aged BabyDance Fertility Lubricant using established methods

- Microbiology studies on newly manufactured and aged BabyDance Fertility Lubricant, as follows:

    * Total aerobic microbial count testing per USP <61>
    * Total yeast and mold count per USP <61>
    * Absence of pathogenic organisms (*Escherichia coli, Staphylococcus. aureus, Salmonella, Pseudomonas aeruginosa,* and *Candida albicans*) testing per USP <62>
    * Antimicrobial effectiveness testing per USP <51>
    * Endotoxin testing per USP <85>

- Biocompatibility studies on newly manufactured BabyDance Fertility Lubricant, as follows:

    * Cytotoxicity testing per 10993-5:2009
    * Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
    * Skin Irritation testing per ISO 10993-10:2010
    * Vaginal Irritation testing per ISO 10993-10:2010
    * Acute Systemic Toxicity testing per ISO 10993-11:2006

- Biocompatibility studies on the applicator, as follows:

    * Cytotoxicity testing per 10993-5:2009
    * Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
    * Vaginal Irritation testing per ISO 10993-10:2010

- Mouse embryo assay (MEA) testing on newly manufactured and aged BabyDance Fertility Lubricant

    One-cell mouse embryos were exposed to culture medium with and without added lubricant. Post exposure, mouse embryos were cultured and the percent developing to the expanded blastocyst stage were compared between control and lubricant-exposed treatments.

- Human sperm survival assay (HSSA) testing on freshly manufactured and aged BabyDance Fertility Lubricant

    Washed human sperm were resuspended in medium with and without added lubricant and incubated. Following incubation, progressive motility was compared for sperm in both the control and lubricant-exposed treatments.

- Sperm function testing on freshly manufactured BabyDance Fertility Lubricant, as follows:

* Lubricant barrier assay

  Neat human semen samples were allowed to liquefy. An aliquot of undiluted lubricant was placed on a warmed glass slide. Immediately adjacent to this lubricant, a sample of sperm in semen was placed on the slide. Sperm penetration from semen into the lubricant was evaluated at the sperm-lubricant boundary and at distances into the lubricant samples.

* Bovine mucosal penetration testing

  Capillary tubes were filled with ovulatory phase bovine cervical mucus and sealed at one end. The open end of each tube was placed into a bull sperm sample suspended in either control medium or medium mixed with lubricant. Distance travelled by the vanguard sperm and density of spermatozoa at specified positions in the capillary tube were compared between the two groups.

* Computer assisted sperm analysis (CASA)

  Human sperm samples were incubated with control medium or a medium and lubricant mixture. After incubation and thorough mixing of samples, replicate aliquots were removed from treatments for CASA using a Hamilton Thorne IVOS analyzer. Results were compared between the two groups.

* Semen assessment

  Neat human semen samples were mixed with either control medium or a medium and lubricant mixture and incubated. Following incubation, motility of sperm in both treatments was determined according to the World Health Organization (WHO) guidelines for the examination and processing of human semen.

* Sperm Chromatin Structure Assay (SCSA)

  Neat human semen samples were incubated in control medium or in a medium and lubricant mixture. Human sperm chromatin integrity in both treatments was compared (i.e. DNA fragmentation Index), using the Sperm Chromatin Structure Assay (SCSA). The SCSA was performed using acridine orange to stain single and double stranded nucleic acids in sperm with and without lubricant exposure.

* Mouse In-vitro Fertilization-Embryo Development (mIVF-MEA)

The impact of lubricant on the ability of sperm to penetrate and fertilize oocytes, as well as the ability of resulting zygotes to then develop normally to the blastocyst stage was evaluated using mIVF-MEA. Mouse ova were placed with mouse sperm in a solution containing control medium or a medium and lubricant mixture. After fertilization incubation, presumptive zygotes were transferred to culture medium for subsequent development to expanded blastocysts. The number of oocytes becoming fertilized and developing into expanded blastocysts was compared between the two groups.

- mIVF-MEA testing on BabyDance Lubricant filled in freshly manufactured and aged applicator

  The impact of lubricant exposed to applicators on the ability of sperm to penetrate and fertilize oocytes, as well as the ability of these zygotes to then develop to the blastocyst stage was evaluated using mIVF-MEA. Mouse ova were placed with mouse sperm from three different treatments including: control medium (no lubricant or applicator exposure); medium and lubricant (without applicator exposure); medium and lubricant following exposure to the applicator. After fertilization incubation, the presumptive zygotes were transferred to culture medium for development to expanded blastocysts. The number of oocytes becoming fertilized and developing to expanded blastocysts was compared between the treatments.

- Condom compatibility testing on freshly manufactured BabyDance Fertility Lubricant per ASTM D7661-10

VIII. Conclusion

The subject and predicate devices have the same intended use and the different technological characteristics do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.