DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 4, 2017

Good Clean Love
% Steve Hesler
Principal Consultant
S. Hesler Compliance Engineering
2602 5th Avenue
West Linn, OR 97068

Re: K162207
Trade/Device Name: Good Clean Love - BIO-pHRESH
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 6, 2017
Received: April 7, 2017

Dear Steve Hesler:

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,

Joyce M. Whang -S

for

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: 0MB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

51O(k) Number *(if known)*

K162207

Device Name

Good Clean Love - BIO-pHRESH

Indications for Use *(Describe)*

Good Clean Love BIO-pHRESH 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. It is not compatible with polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D) **XX** Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – BIO-pHRESH

Date prepared:
May 1, 2017

Submitter:
Good Clean Love, Inc.
207 West Avenue
Eugene, OR 97401

Contact Person:
Wendy Strgar
Ph: 541-344-4483
Fax: 541-685-1335

Proprietary name:
Good Clean Love BIO-pHRESH

Classification
Common Name: Personal Lubricant
Classification Name: Condom (CFR 884.5300)
Product code: NUC (lubricant, personal)
Regulatory Class: II

Intended use:
Good Clean Love BIO-pHRESH 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. It is not compatible with polyurethane condoms.

Predicate Device:
The Good Clean Love BIO-pHRESH Moisturizing Vaginal Lubricant is substantially equivalent to Good Clean Love's Almost Naked and Cinnamon Vanilla personal lubricants (K150094). Neither of these predicate products has been subject to a design-related recall.

Description of device:
Good Clean Love BIO-pHRESH contains water-solvent materials. The primary ingredient (95%) is aloe vera and it includes aromatics of apple. The product is provided in tube container and has a gel consistency. It is supplied with a vaginal applicator. 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.

The product is formulated to match the osmolality and pH found in the human vagina.

Summary of technological characteristics compared to predicate devices:

Both the Good Clean Love BIO-pHRESH and its predicate device, Good Clean Love Almost Naked/Cinnamon Vanilla, consist of 95% organic aloe vera, include xanthan as a thickener, and the preservatives potassium sorbate and sodium benzoate in small amounts. Both products include aromatics to enhance sensory perceptions. Both products are compatible with latex and polyisoprene condoms.

The differences in formulation between the subject and predicate devices do not raise different questions of safety or effectiveness.

Summary of non-clinical performance testing:

BIO-pHRESH has been tested and found compatible with latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

Antimicrobial effectiveness has been demonstrated per USP <51>. Testing has established that the subject lubricant met specifications for appearance, color, odor, texture, pH, specific gravity, viscosity and osmolality.

Biocompatibility has been demonstrated to show that the product meets requirements for cytotoxicity, sensitization, irritation, and acute systemic toxicity using ISO10993 methods or alternate testing methodologies.

Shelf-life has been established at one-year.

Conclusion:

The results of the testing described above demonstrate that BIO-pHRESH personal lubricant is as safe and effective as the predicate devices and supports a determination of substantial equivalence.