July 9, 2018

Perrigo New York, Inc.
% Phil Triolo, Ph.D., RAC
Principal Consultant
Phil Triolo and Associates LC
86 Skycrest Lane
Salt Lake City, UT 84108

Re: K180923
Trade/Device Name: Personal Lubricating Jelly
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 6, 2018
Received: April 10, 2018

Dear Phil Triolo:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180923

Device Name
Personal Lubricating Jelly

Indications for Use *(Describe)*
This device is 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 device is compatible with natural rubber latex condoms and not compatible with polyurethane and polyisoprene 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."

K180923 – 510(k) Summary

1. Submitter

Perrigo New York, Inc.
1700 Bathgate Ave.
Bronx, NY 10457-7512

Submitted By
Karen Dombrowski, Sr. Regulatory Affairs Project Manager, Monograph
Perrigo Company
515 Eastern Avenue, Allegan MI 49010
269-673-9149 (Phone)
269-673-1223 (Fax)
karen.dombrowski@perrigo.com (email)

Contact Person / Prepared By
Phil Triolo, PhD, RAC
President and Principal Consultant
Phil Triolo and Associates LC
801 699 9846 (phone) / 801 328 2399 (fax)
philt@philt.com (email)

Date Prepared
4 July 2018

2. Subject Device

Trade Name
Personal Lubricating Jelly

Common Name
Personal Lubricant

Classification
Regulation name: Condom
Regulation number: 21 CFR 884.5300
Regulatory Class: II
Product Code: NUC (lubricant, personal)

3. Predicate Device

Personal Lubricating Jelly (K012203)

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

4. Device Description

Personal Lubricating Jelly is a water-based personal lubricant containing ingredients that are commonly used in vaginal lubrication devices, including water, glycerin, hydroxyethylcellulose, chlorohexidine gluconate, glucono delta lactone, methylparaben, and sodium hydroxide. It is provided non-sterile.

5. Indications for Use

This device is 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 device is compatible with natural rubber latex condoms and not compatible with polyurethane and polyisoprene condoms.

Both the subject and predicate devices have the same intended use.

6. Technological Comparison with Predicate Device

The subject and predicate device have the same formulation and specifications. The only difference between the two devices is their condom compatibility statement. The predicate device made no claims related to condom compatibility, whereas the subject device claims to be compatible with natural rubber latex condoms (and not compatible with polyurethane and polyisoprene condoms). This difference in technological characteristics does not raise different questions of safety or effectiveness.

7. Performance Data

The only difference between the new Personal Lubricating Jelly and the already cleared Personal Lubricating Jelly is that device labeling will be modified to add a statement that the Personal Lubricating Jelly is compatible with natural rubber latex condoms. This statement is supported by performance data collected in accordance with ASTM7661-10, Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms, an FDA-recognized Consensus Standard.

8. Conclusion / Summary of Substantial Equivalence

Based on the information and data provided and analyzed in this 510(k) premarket notification, the Personal Lubricating Jelly is substantially equivalent to the predicate device.