



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2016

Empowered Products, Inc.
% Judy Burton
President
Advena Usa, LLC
3010 LBJ Frwy., 12th Floor
Dallas, TX 75234

Re: K152918
Trade/Device Name: Gun Oil, Pink, Gun Oil H2o, Pink Water
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: April 21, 2016
Received: May 6, 2016

Dear Judy Burton,

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 yours,


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

Indications for Use

510(k) Number (if known)

K152918

Device Name

Gun Oil silicone lubricant, Pink silicone lubricant for Women, Gun Oil H20 water-based lubricant, Pink water-based lubricant for Women

Indications for Use (Describe)

Gun Oil silicone lubricant is a personal lubricant intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity. This product is compatible with polyurethane condoms. This product is not compatible with polyisoprene or natural rubber latex condoms.

Pink silicone lubricant for women is a personal lubricant intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity. This product is compatible with polyurethane condoms. This product is not compatible with polyisoprene or natural rubber latex condoms.

Gun Oil H20 water-based is a personal lubricant intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity. This product is compatible with polyisoprene condoms. This product is not compatible with polyurethane or natural rubber latex condoms.

Pink Water water-based lubricant for women is a personal lubricant intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity. This product is compatible with polyisoprene condoms. This product is not compatible with polyurethane or natural rubber latex 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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