February 5, 2018

ImQuest BioSciences, Inc.
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr. NE
Saint Petersburg, FL 33704

Re: K171516
Trade/Device Name: FLIP Lube
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: January 3, 2018
Received: January 4, 2018

Dear Paul Dryden:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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

510(k) Number *(if known)*

K171516

Device Name

FLIP Lube

Indications for Use *(Describe)*

FLIP Lube is personal lubricant for penile, vaginal, and/or rectal 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 synthetic polyisoprene condoms. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Submitter: ImQuest BioSciences Inc.
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Frederick, MD 21704
Tel – 301-696-0274

Official Contact: Karen W. Buckheit - Director, Prevention Sciences, ImQuest BioSciences Inc.

Proprietary or Trade Name: FLIP Lube

Common/Usual Name: Personal Lubricant

Classification Name 21 CFR 884.5300 (Condom)
NUC (lubricant, personal)
Class II

Predicate Device: K141913 - PJUR GROUP LUXEMBOURG SA – Backdoor Anal Glide /Analyse Me!

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

Device Description:
FLIP Lube is a water-based, personal lubricant used to provide lubrication during sexual intercourse. It is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms.

The specifications include appearance, color, odor, pH, viscosity, osmolality, antimicrobial effectiveness, total aerobic microbial count, total yeast and mold count, and absence of pathogenic organisms.

Indications for Use:
Flip Lube is personal lubricant for penile, vaginal, and/or rectal 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 synthetic polyisoprene condoms. Not compatible with polyurethane condoms.

Substantial Equivalence Discussion:

Feature	**Predicate K141913 PJUR GROUP LUXEMBOURG SA - Backdoor Anal Glide /Analyse Me!**	**Proposed K171516 ImQuest BioSciences FLIP Lube**
Product Classification	21CFR 884.5300 - NUC – Personal Lubricant	
Class	II / OTC	
Indications for Use	Personal lubricants for penile, vaginal, and/or anal application intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication	FLIP Lube is personal lubricant for penile, vaginal, and/or rectal 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

510(k) Summary – K171516
Date Prepared: 5-Feb-18

		natural rubber latex and synthetic polyisoprene condoms. Not compatible with polyurethane condoms.
Environment of Use	OTC – home use	OTC – home use
Condom Compatibility	Natural rubber latex	Natural rubber latex Polyisoprene Not compatible with polyurethane condoms.
Type of lubricant	Water-based Silicone-based	Water-based
Materials	Dimethicone Dimethiconol Simmondsia Chinensis (Jojoba) Seed Oil Amyris Balsamifera Bark Oil	Water Glycerol Hydroxyethyl Cellulose Methylparaben Propylparaben Sodium Phosphate

Both lubricants have the same intended use, but different technological characteristics (e.g., base type). The different technological characteristics do not raise different questions of safety and effectiveness.

Summary of Performance Testing

The following performance tests were conducted:

- Shelf Life (accelerated aging equivalent to 12 months per ASTM F1980-16)
- Condom Compatibility per ASTM D7661-10
- Biocompatibility
    - Cytotoxicity (ISO 10993-5:2009)
    - Sensitization (ISO 10993-10:2010)
    - Vaginal Irritation with Histopathology (ISO 10993-10:2010)
    - Acute Systemic Toxicity (ISO 10993-11:2006)

The results of performance testing demonstrate that the proposed lubricant maintains all of its specifications over the duration of its proposed shelf life, is compatible with natural rubber latex and polyisoprene condoms, but not polyurethane condoms, and biocompatible.

Conclusion
Based upon performance testing provided, the proposed device and predicate device are substantially equivalent.