DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 11, 2016

Toaster Labs, Inc
Amy Buckalter
CEO
2212 Queen Anne Avenue North, #269
Seattle, WA 98109

Re: K152628
Trade/Device Name: Pulse H20h!
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: May 27, 2016
Received: May 31, 2016

Dear Amy Buckalter,

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

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)*
K152628

Device Name
Pulse™ H2Oh!

Indications for Use *(Describe)*

The Pulse™ H2Oh! personal lubricant is intended for vaginal and/or penile application to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication.

This personal lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane 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.

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510(k) Summary – K152628 *Pulse™ H2Oh!*

Company, Device and Predicate Information:

510(k) Owner	Toaster Labs, Inc.
Address	2212 Queen Anne Avenue North, #269 Seattle, WA 98109
Contact person	Amy C. Buckalter, CEO
Contact numbers	Phone: 206-910-8332 Fax: 206-331-4876
510(k) Summary preparation date	May 26, 2016

510(k)	**K152628**
Trade Name	***Pulse™ H2Oh!***
Common Name	Personal lubricant
Device Classification	*Regulation*: 21 CFR 884.5300 – Lubricant, personal *Class*: Class II *FDA product code*: NUC

Predicate Device	*Name*: LifeStyles® Smooth™ 2-in-1 Massage & Lubricant *510(k) number*: K122476 *Manufacturer*: Ansell Healthcare Products, LLC *Regulation*: 21 CFR 884.5300 – Lubricant, personal *Class*: Class II *FDA product code*: NUC

***Device Description*:** The Pulse H2Oh! is a personal lubricant intended for over-the-counter sale. It is sold, and used, not sterile. The lubricant is colorless to slightly yellow and unfragranced.

The product is used 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.

The Pulse H2Oh! lubricant is supplied in the form of individual plastic pump canisters, called pods. A pod is ~2.5 inches tall, has a diameter of ~1 inch and contains ~6.7 ml of lubricant. The pod pump allows the user to receive an aliquot of lubricant without touching the nozzle or inside of the container.

The Pulse H2Oh! lubricant is a gel with a pH of 4.8 – 5.2, and is comprised of the following ingredients:

- Purified water
- Propanediol / Zemea Propanediol
- Hydroxyethylcelluose / Natrosol 250H Pharm
- Potassium Sorbate
- Chia Seed Extract
- Citric Acid

Device specifications are: color, odor, appearance, weight gain/loss % (w/w), pH, specific gravity, viscosity, osmolality, total aerobic microbial count, total yeast and mold count, absence of specified microorganisms (P. aeruginosa, S. aureus and C. albicans) and antimicrobial effectiveness.

Indications for Use:

The Pulse™ H2Oh! personal lubricant is intended for vaginal and/or penile application to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication.

This personal lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

Summary of Technological Characteristics: The subject and predicate device have different technological characteristics, including their formulation, specifications, and condom compatibility. These differences do not raise different questions of safety and effectiveness because these differences are routinely encountered during 510(k) reviews of personal lubricants.

Summary of Testing: Testing of the Pulse H2Oh! lubricant was performed by independent laboratories/test centers and is summarized as follows. As noted below, all testing was found to be acceptable.

- *Condom compatibility Testing* - Test was performed in accordance with ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The lubricant was found to be compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms.

- *Microbiological Testing* - Tested was performed in accordance with the following standards and passed.
  - USP <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration
  - USP <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
  - USP <51> Antimicrobial Effectiveness Testing - category 2

- *Biocompatibility Testing* - Biocompatibility was evaluated in accordance with ISO 10993 - Biological Evaluation of Medical Devices. Tests for cytotoxicity, vaginal irritation, sensitization, and acute systemic toxicity were completed and passed.
  - Acute Systemic Toxicity: ISO 10993-11:2006
  - Cytotoxicity: ISO 10993-5:2009
  - Vaginal Irritation Testing: ISO 10993-10:2010
  - Guinea Pig Maximization Test (GPMT): ISO 10993-10:2010

- *Shelf life* - The shelf life of Pulse H2Oh! is 10 months. This is based on the results of real time aging studies that demonstrated that the device maintains its specifications over the duration of its shelf life.

Conclusion: The Pulse H2Oh! is substantially equivalent to the predicate device. Both the Pulse H2Oh! and the predicate have equivalent intended uses and the same basic technological characteristics. Differences in technological characteristics do not introduce different questions regarding safety or effectiveness.