DEC - 8 2011

K110325
29. 1 of 2

510(k) SUMMARY

Submitter	Mayer Laboratories, Inc. 1950 Addison Street, Suite 101 Berkeley, CA 94704-1182 USA
Contact Person	David P. Mayer, President (510) 229-5300 telephone (510) 848-5763 fax davidm@mayerlabs.com email
Date Prepared	February 1, 2011
Proprietary Name	Aqua Lube® (TX 407)
Common Name	Personal Lubricant
Classification Name	Condom Class II (21 CFR § 884.5300) Product Code: NUC, Lubricant, patient, vaginal, latex compatible
Predicate Device	K-Y® Personal Lubricant (K955648) ForPlay Personal Lubricant (K051688)
Description of Device	Aqua Lube® is a non-sterile, water-based, personal lubricant designed to supplement the body's own natural lubrication fluids. This product is a clear, non-greasy, high-viscosity, liquid. This product may be used with or without a condom during intimate sexual activity.

Indications For Use

Aqua Lube Personal Lubricant 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, polyisoprene, and polyurethane condoms.

Technological Characteristics
The Aqua Lube formula is proprietary. The product however, has no exceptional technological characteristics. Aqua Lube Personal Lubricant consists mainly of water and water-soluble ingredients similar to other lubricants currently on the U.S. market and substantially equivalent to the predicate devices.

Substantial Equivalence
Aqua Lube is substantially equivalent to predicate devices currently marketed in the United States, including K-Y Personal Lubricant and ForPlay Personal Lubricant. Aqua Lube and the predicate devices have the same intended use and have similar formulations. The safety of the ingredients and of the finished products based on laboratory studies is substantially equivalent.

Safety Testing
Biocompatibility and Toxicity studies on Aqua Lube Personal Lubricant were conducted by outside laboratories, in compliance with Good Laboratory Practices (GLPs). The proposed devices were evaluated, for their potential to cause cytotoxicity, irritation, sensitization, and systemic toxicity and the results of testing showed that this formula meets acceptance requirements for all tests. Additionally, studies on latex condom compatibility were conducted. According to the data, Aqua Lube does *not* affect the mechanical or physical integrity of natural rubber latex, polyisoprene, and polyurethane condoms. Therefore, Aqua Lube is safe to use with latex condoms and non-latex condoms.

Conclusion
Laboratory and safety testing conducted on Aqua Lube personal lubricant has provided scientific evidence that this product is safe for its intended use, and that it is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC - 8 2011

Mr. David P. Mayer
President
Mayer Laboratories, Inc.
1950 Addison Street, Suite 101
BERKELEY CA 94704

Re: K110325
Trade/Device Name: Aqua Lube® (TX-407)
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 21, 2011
Received: November 23, 2011

Dear Mr. Mayer:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number K110325

Device Name Aqua Lube®

Indications for Use Aqua Lube Personal Lubricant 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, polyisoprene and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110325