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	July 26, 2013
Proprietary Name	Aqua Lube® Natural Lubricants
Common Name	Personal Lubricant
Classification Name	Condom Class II (21 CFR § 884.5300) Product Code: NUC
Predicate Device	Glycerin & Paraben Free Astroglide® (K072647)
Description of Device	Aqua Lube® Natural Personal Lubricant is a non-sterile, water-based, personal lubricant designed to supplement the body's own natural lubrication fluids. Aqua Lube® Natural Personal Lubricant consists of two models: "Regular" and "Warming." This product is a clear, non-greasy, high-viscosity, liquid. This product is composed primarily of organic aloe, hydroxyethycellulose, sorbitol, and tocopherols (vitamin E). The Warming model contains the same ingredients as the Regular model plus the additional ingredient organic peppermint oil. Aqua Lube® Natural Personal Lubricant causes a warming response. This product may be used with or without a condom during intimate sexual activity. This product is packaged in a tube made of low density polyethylene with a polypropylene cap. Tube sizes included 1 oz., 2.5 oz, and 4.0 oz. Each tube is packaged in a paperboard carton, which constitutes the device's individual carton.

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Intended Use
Aqua Lube® Natural 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

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

Product Safety
Biocompatibility testing was conducted on Aqua Lube® Natural Personal Lubricant per ISO 10993 series, in compliance with Good Laboratory Practices (GLPs). The proposed devices were evaluated for their potential to cause cytotoxicity, irritation, sensitization, and acute systemic toxicity. The results of testing showed that the device meets acceptance requirements for all tests, as summarized in the following table:

Testing Performed	Results
Cytotoxicity	Non-cytotoxic
Rabbit Vaginal Irritation	Non-Irritating
Acute Systemic Toxicity	Non-systemically toxic
Sensitization Guinea Pig Maximization	Non-sensitizing

Condom Compatibility
Studies on condom compatibility were conducted according to the ASTM D7661-10. Both models of Aqua Lube® Natural Personal Lubricant demonstrated they do *not* affect the mechanical or physical integrity of natural rubber latex and polyisoprene condoms. The studies did show both models did affect polyurethane condoms. Therefore, Aqua Lube® Natural Personal Lubricant is compatible with natural rubber latex condoms and polyisoprene condoms. Aqua Lube® Natural Personal Lubricant is not compatible with polyurethane condoms.

Shelf Life Data
Real time stability data confirms a minimum shelf life of 24 months for the Aqua Lube® Natural Lubricants – Warming Model and 14 month stability for Aqua Lube® Natural Personal Lubricant – Regular Model.

Substantial Equivalence
Aqua Lube® Natural Personal Lubricant and the predicate device have the same intended use. Both are water-based personal lubricants and they have comparable physical parameters. The Aqua Lube® Natural Personal Lubricant is substantially equivalent to predicate device regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 1, 2013

Mayer Laboratories, Inc.
% David P. Mayer
President and CEO
1950 Addison Street, Suite 101
Berkeley, CA 94704-1182

Re: K130345
Trade/Device Name: Aqua Lube® Natural Personal Lubricant
Aqua Lube Natural Personal Lubricant has two variants
1) Regular
2) Warming
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 18, 2013
Received: June 28, 2013

Dear David P. 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 -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

INDICATIONS FOR USE STATEMENT

510(k) Number	**K130345**
Device Name	**Aqua Lube® Natural Personal Lubricant** Aqua Lube Natural Personal Lubricant has two variants 1) Regular 2) Warming
Indications for Use	Aqua Lube® Natural 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 and polyisoprene condoms. This product is not compatible with 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)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130345