JUL 21 2014

II. 510(k) Summary
Azul Personal Lubricant

Submitter Name:	Church & Dwight Co., Inc.
Submitter Address:	500 Charles Ewing Boulevard Ewing, NJ 08628
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Date Prepared:	July 21, 2014
Device Trade Name:	Azul Personal Lubricant
Device Common Name:	Personal Lubricant
Product Code:	NUC – Condom (21 CFR § 884.5300)
Classification:	Class II
Predicate Devices:	Lifestyles Natural (K122054) Aloe Cadabra Lubricant (K124044)
Device Description:	The Azul Personal Lubricant is a hydrous, clear water-based personal lubricant with aloe and vitamin E that is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. The lubricant formula is thickened using sodium hyaluronate and hydroxyethylcellulose. It contains a pH buffer system to maintain a slightly acidic pH of 5.9 to 6.9, and is preserved using methylparaben. This medical device is designed to meet product specifications which include:

(continued on next page)

- Color/appearance
- Odor
- pH
- Viscosity
- Methylparaben assay
- Osmolality
- Total aerobic microbial count
- Total yeast and mold count
- Absence of pathogenic organisms
- Antimicrobial effectiveness

The Azul Personal Lubricant is packaged in a polyethylene terephthalate (PET) bottle with a screw on, flip top polypropylene (PP) closure. An induction seal will be placed over the bottle for tamper resistance and preservation.

Intended Use:

The intended use is as a personal lubricant compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.

Indications for Use:

Azul Personal Lubricant is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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:

Azul Personal Lubricant contains similar ingredients as legally marketed water-based personal lubricants that are compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Summary of Studies:

Biocompatibility studies – Performed on the final 510(k)-subject device. These studies include in vitro cytotoxicity study; rabbit vaginal irritation study; rabbit penile irritation study; acute systemic toxicity study; guinea pig maximization sensitization study; primary rabbit skin irritation study. Based on the results of these studies, Azul Personal Lubricant is considered safe for consumer use.

Shelf life – Stability and shelf life testing was performed on the Azul Personal Lubricant to validate the stability of the device during its intended shelf life of 2 years. Accelerated aging was performed in accordance with accepted standards for medical devices to simulate long-term storage. To evaluate stability, this in vitro study used sealed and unsealed sample bottles to simulate actual device usage.

Condom compatibility – The results for laboratory testing using a modification of the methodology found in ASTM D7661; Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. Laboratory test results demonstrated that the proposed device is compatible with leading commercial brands of natural rubber latex and polyisoprene condoms, but not compatible with polyurethane condoms.

Substantial Equivalence: The proposed device is substantially equivalent to the predicate devices, Lifestyles Natural and Aloe Cadabra in technology, intended use, safety.

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

July 21, 2014

Church & Dwight Co., Inc.
Joseph Ciccone
Senior Manager, Regulatory Affairs
500 Charles Ewing Boulevard
Ewing, NJ 08628

Re: K141034
Trade/Device Name: Azul Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: April 21, 2014
Received: April 22, 2014

Dear Joseph Ciccone,

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" (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 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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

I. Indications for Use

510(k) Number (if known): N/A

Device Name: Azul Personal Lubricant

INDICATIONS FOR USE:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ (21 CFR 801 Subpart D)

OR

Over-The-Counter (OTC) _X_ (21 CFR 801 Subpart C)

Benjamin R. Fisher -S
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