510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants is provided below.

Device Common Name:	Personal Lubricant
Device Proprietary Name:	Aloe Cadabra® Personal Lubricant – Natural Aloe Aloe Cadabra® Personal Lubricant – Pina Colada Aloe Cadabra® Personal Lubricant – Tahitian Vanilla Aloe Cadabra® Personal Lubricant – French Lavender Aloe Cadabra® Personal Lubricant – Peppermint
Submitter:	Seven Oaks Ranch, Inc. 2658 Channel Drive Ventura, CA 93003
Contact:	Calley Herzog, consultant Biologics Consulting Group, Inc. Phone: 720-883-3633 Fax: 720-293-0014 Email: cherzog@bcg-usa.com
Date Prepared:	**July 12, 2013**
Classification Regulation:	884.5300
Classification Name:	Condom
Panel:	Obstetrics/Gynecology
Product Code:	NUC
Predicate Device:	K061466 - INTIMOL™ Liquid Personal Lubricant (DLC Laboratories, Inc.)

AUG 30 2013

Indication for Use:
Aloe Cadabra® Lubricant and Aloe Cadabra® Flavored/Scented Lubricants are personal lubricants, 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.

Device Description:
Aloe Cadabra® Lubricant and Aloe Cadabra® Flavored/Scented Lubricants are non-sterile, aloe-based vaginal lubricants designed to supplement the body's own natural lubrication fluids,

and to enhance the ease and comfort of intimate sexual activity. Aloe Cadabra® Lubricant and Aloe Cadabra® Flavored/Scented Lubricants are specifically formulated with 95% organic aloe. The remaining five percent of ingredients are in all cases food grade and in many cases certified organic. This device is not a contraceptive or spermicide, nor does it contain any such component. All ingredients in Aloe Cadabra Flavored/Scented Lubricants are GRAS (Generally Recognized as Safe by FDA). The specifications for the Aloe Cadabra Lubricants include appearance, odor, pH, viscosity, osmolality, total microbial count, fungal/yeast/mold limits, and absence of pathogenic organisms (straphylococcus aureus, pseudomonas aeruginosa, escheria coli, salmonella, bile tolerant gram negative bacteria, c. albicans and clostridia).

The product is bottled in an HDPE opaque white plastic bottle with a white flip top cap. The bottle is packaged into a carton for sale to consumers. The product comes in five varieties of scents and flavors including Natural Aloe, Pina Colada, Tahitian Vanilla, French Lavender, and Peppermint.

Performance Data:
Biocompatibility studies including Acute System Toxicity, Vaginal Irritation Testing, Cytotoxicity, and Skin Sensitization were performed according to ISO 10993 standards.

Acute Systemic Toxicity: This test evaluated systemic responses in mice after injection of Aloe Cadabra® Lubricant. The test was conducted according to ISO 10993-11: 2006 standards. All test group animals survived the test period and none of the test group animals exhibited any biological reactivity at any of the tested time points.

Vaginal Irritation Testing: The potential of Aloe Cadabra® Lubricant to produce irritation of the vaginal mucosal tissue was assessed according to ISO 10993-10: 2010 standards. Results of the testing show that Aloe Cadabra® Lubricant was considered non-irritating to the vaginal mucosa in female New Zealand White Rabbits.

Cyotoxicity: Aloe Cadabra® Lubricant was not considered to have a cytotoxic effect according to the qualitative evaluation of cells exposed to Aloe Cadabra® Lubricant based on grading criteria in ANSI/AAMI/ISO 10993-5: 2009.

Skin Sensitization: Maximization testing for delayed hypersensitivity was performed to determine to what extent Aloe Cadabra® Lubricant has the potential to act as a contact sensitizer in guinea pigs. This test was completed according to methods detailed in ISO 10-993-10: 2010. According to methods detailed in ISO 10-993-10: 2010, Aloe Cadabra® Lubricant did not elicit sensitization reactions in the animals used in the study.

Shelf Life: The Aloe Cadabra® Lubricants have a two-year shelf life based on the results of a real time aging study.

Condom Compatibility: The compatibility of the Aloe Cadabra® Lubricants was evaluated with natural rubber latex, polyisoprene, and polyurethane condoms per ASTM D7661-10. The condom compatibility testing was performed on all 5 versions of the lubricants. The testing showed that the lubricants are compatible with natural rubber latex and polyisoprene condoms and are not compatible with polyurethane condoms.

Conclusions drawn from Testing Performed: The non-clinical performance testing conducted demonstrates that the Aloe Cadabra Personal Lubricants are substantially equivalent to the proposed predicate device.

Substantial Equivalence:
Based on similar intended uses, similar technological characteristics and similar testing, the Aloe Cadabra® Lubricant and Aloe Cadabra® Flavored/Scented Lubricants can be found substantially equivalent to the INTIMOL™ Liquid Personal Lubricant (K061466).

Device Comparison Table

	K124044	**K061466**
Device Name	Aloe Cadabra Personal Lubricant – Natural Aloe Aloe Cadabra Personal Lubricant – Pina Colada Aloe Cadabra Personal Lubricant – Tahitian Vanilla Aloe Cadabra Personal Lubricant – French Lavender Aloe Cadabra Personal Lubricant – Peppermint	INTIMOL Liquid Personal Lubricant
Manufacturer	Seven Oaks Ranch, Inc.	DLC Laboratories, Inc.
Classification	884.5300	884.5300
Product Code	NUC	NUC
Indication	Aloe Cadabra® Lubricant and Aloe Cadabra® Flavored/Scented Lubricants are personal lubricants, 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.	INTIMOL™ Liquid Personal Lubricant is principally intended as personal lubricant to supplement the body's natural lubricating fluids, and to enhance the ease and comfort of intimate sexual activity with or without a latex condom.
Over-the-Counter Use	Yes	Yes
Contains Aloe	Yes	Yes
Provided Sterile	No	No
Biocompatible	Yes	Yes

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 30, 2013

Seven Oaks Ranch, Inc.
% Calley Herzog
Consultant
Biologics Consulting Group, Inc.
400 North Washington Street, Suite 100
Alexandria, VA 22314

Re: K124044
Trade/Device Name: Aloe Cadabra Personal Lubricant – Natural Aloe, Aloe Cadabra Personal Lubricant – Pina Colada, Aloe Cadabra Personal Lubricant – Tahitian Vanilla, Aloe Cadabra Personal Lubricant – French Lavender, Aloe Cadabra Personal Lubricant - Peppermint
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: July 17, 2013
Received: July 18, 2013

Dear Calley Herzog:

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 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. 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 (if known): K124044

Device Name:
Aloe Cadabra Personal Lubricant - Natural Aloe
Aloe Cadabra Personal Lubricant - Pina Colada
Aloe Cadabra Personal Lubricant - Tahitian Vanilla
Aloe Cadabra Personal Lubricant - French Lavender
Aloe Cadabra Personal Lubricant - Peppermint

Indications For Use:
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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
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