II. 510(k) Summary

JUN 2 8 2013

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Date Prepared:	May 28, 2013
510(k) Number:	K123427
Device Trade Name:	Nirvana D Personal Lubricant
Device Common Name:	Personal Lubricant
Product Code:	NUC – Condom (21 C.F.R. § 884.5300)
Classification:	Class II
Predicate Device:	K-Y® Brand Intrigue™ Intense Warming Sensation (K072360)
Intended Use:	Nirvana D 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. Not compatible with polyurethane or other condoms.
Device Description:	The Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant composed of dimethicone, dimethiconol, vanillyl butyl ether ("VBE") and hexyl nicotinate. Nirvana D Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not a spermicide or a contraceptive. The product is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, flip top polypropylene (PP) closure constituting the device's primary packaging. One bottle is packaged into a cardboard carton, which constitutes the device outer packaging.

Technological Characteristics:

There is no difference in the fundamental technological characteristic of the Nirvana D Personal Lubricant and the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant. Nirvana D Personal Lubricant is composed of dimethicone, dimethiconol, vanilly butyl ether, and hexyl nicotinate. The proposed device is substantially equivalent to the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant cleared under 510(k) # K072360. Three of the four ingredients, dimethicone, dimethiconol, and vanillyl butyl ether, in Nirvana D Personal Lubricant are identical to those in the predicate device. The additional ingredient, hexyl nicotinate, does not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009.

Testing Performed:

Testing Performed	Results
Cytotoxicity	Non-cytotoxic
Rabbit Vaginal Irritation	Non-irritating
Rabbit Penile Irritation	Non-irritating
Acute Systemic Toxicity	Non-systemically toxic
Guinea Pig Maximization	Non-sensitizing
Primary Rabbit Skin Irritation	Non-irritating

Condom Compatibility:

Condom Compatibility Testing was performed with Nirvana D Personal Lubricant and ASTM D7761-10 "Standard Testing Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" which was modified to include pre-lubricated and un-lubricated dry condoms. Three marketed brands of pre-lubricated and un-lubricated dry natural rubber latex condoms and one brand of polyisoprene condoms were tested.

Condom compatibility testing results demonstrate that Nirvana D Personal Lubricant is compatible with commercially available natural rubber latex condoms and polyisoprene condoms.

Shelf-life:

In order to establish the stability of the proposed device for its intended shelf-life, an accelerated aging stability test was conducted. Evaluation of viscosity, odor, color and appearance was conducted. Microbial evaluation was conducted via USP testing for Total Microbial Count, Total Yeast and Mold count and Absence of Microbial Pathogens. Satisfactory results were obtained for all parameters evaluated.

Based on the results of the accelerated aging study and microbial testing, Nirvana D Personal Lubricant has a proposed shelf-life of two-years.

A Real-Time aging study is being performed in order to verify results of the accelerated aging study.

Substantially Equivalence:

Based on non-clinical performance data, biocompatibility review and testing and safety data, the proposed device is substantially equivalent to K-Y® Brand Intrigue™ Intense Warming Sensation in technology, intended use, safety and effectiveness.

Conclusion:

The results from laboratory testing and non-clinical evaluation of human use testing show that the proposed device performs equivalently to the predicate device and is safe for use as a personal lubricant.

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

June 28, 2013

Church & Dwight Co., Inc.
% Ms. Emily Perez
Senior Regulatory Affairs Specialist
469 North Harrison Street
PRINCETON NJ 08543

Re: K123427
Trade/Device Name: Nirvana D Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 28, 2013
Received: May 30, 2013

Dear Ms. Perez:

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

I. Indications For Use

510(k) Number (if known): K123427

Device Name: Nirvana D 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 ____	OR	Over-The-Counter Use __X__
(Part 21 C.F.R. 801 Subpart D)		(21 C.F.R. 801 Subpart C)

Herbert P. Lerner -S

K123427