

*II. 510(k) Summary*

FEB - 1 2012

**510(k) SUMMARY**

Submitted by: ONE®  
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Date Prepared: January 19, 2012

Propriety Name: ONE® Personal Lubricant (Water-Based)

Proposed Trade Name: ONE® Oasis

Common Name: Personal Lubricant

Classification Name: Condom  
Class II (21 CFR §884.5300)  
NUC

Predicate Device: Wet Light Personal Moisturizer  
Trigg Laboratories  
510(k) No. K013086

Device Description: ONE® Personal Lubricant (water-based formulation) is a non-sterile, aqueous-based personal lubricant for use with or without a condom. It is specifically formulated to be a clear, non-irritating, non-greasy, odorless, gel-like liquid. This device is not a contraceptive nor does it contain any spermicidal component. Two forms of packaging are intended. The first primary packaging (having direct contact with product) consists of a plastic packaging. The second primary packaging is foil wrappers.

Intended Use: ONE® Personal Lubricant (water-based formulation) is an over-the-counter personal lubricant.



**Indications For Use:** ONE® Oasis 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:** ONE® Personal Lubricant water-based formulation contains water and water-soluble ingredients similar to ingredients found in the predicate device.

**Biocompatibility:**

Biocompatibility testing was performed in accordance with ISO 10993-1.

Testing Performed	Results
Cytotoxicity	Product is Non-toxic
ISO Guinea Pig Maximization Sensitization Test	Product does not elicit a sensitization response
Vaginal Irritation with Histopathology	Product is non-irritating to vaginal tissue
Penile Irritation with Histopathology	Product does not cause penile mucosal irritation
Acute Systemic Toxicity	There is no evidence of system toxicity
Primary Skin Irritation	Dermal irritation response is negligible

**Condom Compatibility:**

Compatibility Testing was performed in accordance with Lubricant Compatibility DRAFT #2010-1 ASTM D11.40.01 04/30/2010 on three marketed brands of Natural Rubber Latex condoms, one brand of Polyisoprene condoms, and one brand of Polyurethane condoms.

The results demonstrated that the condom compatibility testing of the water-based lubricant is compatible with commercially available male condoms made from natural rubber latex, polyurethane, and polyisoprene materials.



**Shelf-Life:**

ONE® Oasis Personal Lubricant (water-based formulation) has a one-year shelf life based on the results of an accelerated aging study. The accelerated aging study evaluated both versions of packaging. The product met specifications.

A real-time aging study is being conducted to confirm results of the accelerated aging study.





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

Ms. Sharon Pietila  
Regulatory Affairs/Quality Assurance Manager  
ONE®  
12 Channel Street  
BOSTON MA 02210

FEB - 1 2012

Re: K110691  
Trade/Device Name: ONE® Oasis Personal Lubricant  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: January 19, 2012  
Received: January 20, 2012

Dear Ms. Pietila:

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.

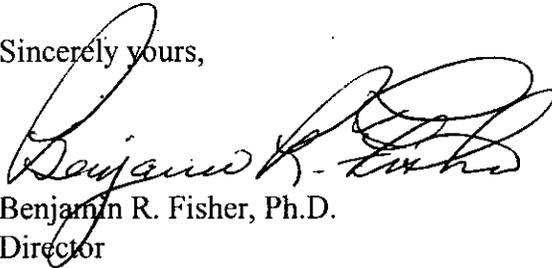
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/CDRHOices/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,



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

**VII. Indications for Use Statement**

**Indications for Use**

510(k) Number: K110691

Device Name: ONE® Oasis Personal Lubricant

Indications For Use:

ONE® Oasis 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)

(Part 21 CFR 801 Subpart C)

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

\_\_\_\_\_  
Consentance of CDRH, Office of Device Evaluation (ODE)

*Benjamin R. Smith*  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and  
Urological Devices

510(k) Number K110691

