DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 22, 2014

Uniderm Farmaceutici S.R.L.
% Guido Bonapace
Consultant
ISEMED S.R.L.
Via A. Altobelli Bonetti 3/A
40026 Imola Bologna, Italy

Re: K132772
Trade/Device Name: Lubrigyn Cream
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 22, 2014
Received: July 25, 2014

Dear Guido Bonapace,

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,

Benjamin R. Fisher -S

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***

***510(k) Number (if known):*** ***K132772***

***Device Name:*** ***LUBRIGYN CREAM***

**Indications for Use:**

LUBRIGYN CREAM 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 not compatible with natural rubber latex, polyisoprene and polyurethane condoms.

| | | |
|---|---|---|
| Prescription Use ____ ___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use ___X ____<br>(21 CFR 801 Subpart C) |

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) Summary for LUBRIGYN CREAM

This 510(k) Summary is submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

## 1. General Information

Submitter: UNIDERM FARMACEUTICI srl is located at:
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Summary Preparation Date: July 22,2014

## 2. Names

Device Name: LUBRIGYN CREAM

Regulation Number 884.5300
Regulation Name Condom
Common Name: Lubricant Personal
Product Code: NUC
Classification: II

## 3. Predicate Device

The LUBRIGYN CREAM is substantially equivalent to the following device:

| Applicant | Device name | 510(k) Number | Product code |
|---|---|---|---|
| POLICHEM SA | me again(r) long lasting vaginal moisturizer, vh essentials (r) long lasting vaginal moisturizer | K112217 | NUC |

LUBRIGYN CREAM and its predicate device are indicated for the same intended use and have equivalent technological characteristics.

## 4. Intended Use

LUBRIGYN CREAM 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 not compatible with natural rubber latex, polyisoprene and polyurethane condoms.

## 5. Device Description

LUBRIGYN CREAM is a non-sterile, non-oily, water based personal lubricant for the intimate vaginal area. LUBRIGYN CREAM is supplied in single use pouches and can be used daily to supplement the body's natural lubrication when vaginal dryness causes discomfort.

The specifications for the LUBRIGYN CREAM include appearance, color, odor, viscosity, density, emulsion stability, osmolality, total microbial count, total yeast and mold count and absence of pathogen organisms (Escherichia Coli, Pseudomonas Aeruginosa, Staphylococcus Aureus, Enterococcus Species, Candida Albicans).

## 6. Technological Characteristics

The LUBRIGYN CREAM formula is proprietary. The product however consists of water based ingredients with an action comparable to other lubricants currently on the market. LUBRIGYN CREAM is substantially equivalent to the predicate device with respect to intended use and technological characteristics

## 7. Summary of Performance Data

**Biocompatibility Testing:** the following biocompatibility tests were performed on LUBRIGYN CREAM :

- Cytotoxicity according to ISO 10993-5
- Sensitization according to ISO 10993-10
- Vaginal irritation according to ISO 10993-10
- Acute systemic Toxicity according to ISO 10993-11

The results of biocompatibility test showed that LUBRIGYN CREAM can be considered biocompatible.

**Stability Testing:** Stability tests performed on already expired product confirm a shelf life of 36 months for LUBRIGYN CREAM .

**Microbiological Challenge Test**: a microbiological challenge test according to USP 51 was performed on expired product to confirm anti-microbial effectiveness.

**Condom compatibility testing:** The compatibility of LUBRIGYN CREAM was evaluated with natural rubber latex, polyisoprene, and polyurethane condoms per ASTM D7661-10. The testing showed that the LUBRIGYN CREAM is not compatible with natural rubber latex, polyisoprene and polyurethane condoms.

**Conclusion drawn from testing performed:**

The no-clinical performance testing conducted demonstrates that LUBRIGYN CREAM is substantially equivalent to the proposed predicate device.