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

February 19, 2015

Uniderm Farmaceutici Srl.
% Maurizio Pantaleoni
Consultant
Isamed, Srl.
Via A. Altobelli Bonetti 3/A
40026 Imola (BO)
Italy

Re: K150147
Trade/Device Name: Lubrigyn Cream
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 15, 2015
Received: January 22, 2015

Dear Maurizio Pantaleoni,

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" (21 CFR 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 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150147

Device Name
LUBRIGYN CREAM

Indications for Use *(Describe)*
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

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for LUBRIGYN CREAM – Airless Container

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:
Via E. Ortolani, 211
00125 – ROMA
ITALY

Contact Person: Maurizio Pantaleoni (consultant)
ISEMED srl
Via A. Altobelli Bonetti 3/A
40026 Imola (BO)
Italy
Mob.phone: +39-348-4435155
Telephone: +39-0542-683803
Fax: +39-0542-698456
Email: regulatory@isemed.eu

Summary Preparation Date: January 15, 2015

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 subject device Lubrigyn cream is substantially equivalent to the following predicate device:

Applicant	Device name	510(k) Number	Product code
UNIDERM FARMACEUTICI	LUBRIGYN CREAM (single pocket-sized sachet)	K132772	NUC

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 a 50 mail airless container 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, pH, 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. **Comparison of technological characteristics with the predicate device**

LUBRIGYN CREAM (Airless Container) and its predicate device are indicated for the same intended use and have equivalent technological characteristics:

- identical formulation
- identical bulk manufacturing process
- identical product release specification.

The differences between the two products are:

- LUBRIGYN CREAM (Airless Container) is packaged in a multidose container (50 ml) instead of a 2 ml single pocket size sachet. The Airless container is a 50 ml polypropylene container that prevents air ingress when the product is dispensed through the pump.
- As a consequence of the point above, a new stability study was performed on LUBRIGYN CREAM (Airless container) in order to confirm shelf life (36 months). The study has been performed both on not opened and opened product.
- The labeling has been modified as indicated below:
  - Modification of the quantity on secondary packaging, primary packaging and instruction for use (50 ml instead of 2 ml for 20 sachets)
  - Introduction of a "direction for use" about dosage on secondary packaging, primary packaging and instruction for use in order to inform the user about the number of "pushes" needed to obtain the same quantity of the single pocket-size sachet (2ml)

- Introduction of a tamper evident seal in primary packaging and a tamper evident warning in secondary packaging.

7. Summary of Performance Data

Stability Testing: Stability tests performed on already expired product confirm a shelf life of 36 months for LUBRIGYN CREAM (Airless container). The tests have been performed both on not opened and opened (Half emptied) containers.

8. Conclusions

The performance data summarized above demonstrate that LUBRIGYN CREAM is substantially equivalent to the proposed predicate device (K132772).