DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2017

Oculus Innovative Sciences
Mr. Brian Martin
Director Of Regulatory Affairs And Quality Control
1129 N. McDowell Boulevard
Petaluma, California 94954

Re: K162217
Trade/Device Name: Loyon
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 14, 2017
Received: February 15, 2017

Dear Mr. Martin:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162217

Device Name
Loyon

Indications for Use *(Describe)*

Rx Indication: Under the supervision of a health care professional, LOYON is indicated to manage and relieve the burning, itching, erythema, and scaling experienced with various types of dermatoses, including atopic dermatitis, radiation dermatitis, and seborrhea and seborrheic dermatitis.

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:

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Food and Drug Administration
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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."

1 510(k) SUMMARY

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

I. SUBMITTER

Oculus Innovative Sciences, Inc.
1129 North McDowell Blvd.
Petaluma, CA 94954
Phone: (707) 283-0550
Fax: (707) 283-0551
Contact Person: Brian W. Martin, Director of Regulatory Affairs and Quality Control
Date Prepared: March 17, 2017

Device Manufacturer:
G. Pohl Boskamp GmbH & Co. KG
Kieler Straße 11
D-25551 Hohenlockstedt
Germany

II. DEVICE

Name of Device: LOYON®
Common or Usual Name: Antipruritic Solution
Classification Name: Dressing, Wound, Drug
Regulatory Class: Unclassified, Pre-amendment status
Product Code: FRO

III. PREDICATE DEVICES

Alevicyn SG Antipruritic Gel manufactured by Oculus Innovative Sciences (K152945)
Tropazone manufactured by Akorn Phamaceuticals (K090337)

IV. DEVICE DESCRIPTION

LOYON® is a non-sterile, oily solution, exclusively indicated for topical application. LOYON® is used to manage and relieve burning and itching and scaling experienced with various types of dermatoses. It will be supplied in 15mL or 50mL amber glass bottles with a pump sprayer.

V. INDICATIONS FOR USE

Rx Indication: Under the supervision of a health care professional, LOYON is indicated to manage and relieve the burning, itching, erythema, and scaling experienced with various types of dermatoses, including atopic dermatitis, radiation dermatitis, and seborrhea and seborrheic dermatitis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Submitter/ Holder	**Proposed Device: LOYON® Oculus Innovative Sciences**	**Predicate Device: K152945 Alevicyn SG Gel, Oculus Innovative Sciences**	**Predictae Deive: Tropazone K090337, Akorn Phamaceuticals.**
Indications for Use	**Rx Indication:** LOYON® is indicated to manage and relieve the burning, itching, erythema, and scaling experienced with various types of dermatoses, including atopic dermatitis, radiation dermatitis, and seborrhea and seborrheic dermatitis.	**Rx Indication:** Alevicyn SG Gel is indicated to manage and relieve the burning, itching, erythema, scaling, and pain experienced with various types of dermatoses, including atopic dermatitis, radiation dermatitis, and seborrhea and seborrheic dermatitis. The Alevicyn SG Gel may also be used to relieve the pain of first and second degree burns. Alevicyn SG Gel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.	Tropazone Lotion is used to manage and relieve the burning and itching experienced with various type of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. It helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.
Mechanism of Action	Emollient	Same	Same
Delivery System	Bottle with spray	Bottle with spray	Tube/ Lotion
Sterility	Non-sterile Water Activity USP <1112> Conforming to USP <61>, <62>	Non-sterile Preserved/Conforming to USP <51>	Non Sterile - Preserved

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for LOYON® was conducted in accordance with the FDA biocompatibility guidance issued on June 16, 2016 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. LOYON® was evaluated for cytotoxic, irritating, sensitizing, and leachable effects.

Bench Testing
The following tests were performed to support the performance of LOYON®: visual inspection, odor (sensory), viscosity, functional checks, leakage test, volume check, and microbiological bioburden. LOYON® meets specification and performance characteristics and is substantially equivalent to the predicate devices.

VIII. CONCLUSION

LOYON® is substantially equivalent in intended use, with different technological characteristics, that does not raise different safety and effectiveness questions compared to Alevicyn SG Antipruritic Gel manufactured by Oculus Innovative Sciences, Inc. (K152945) and Tropazone (K090337). Therefore, LOYON® is substantially equivalent to the predicate devices.