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 4, 2015

Oculus Innovative Sciences Incorporated
Mr. Brian W. Martin
Director of Regulatory Affairs and Quality Control
1129 North McDowell Boulevard
Petaluma, California 94954

Re: K143590
Trade/Device Name: Alevicyn SG Antipruritic Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 30, 2015
Received: May 1, 2015

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" (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 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,

Jennifer R. Stevenson -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)*
K143590

Device Name
Alevicyn SG Antipruritic Gel

Indications for Use *(Describe)*
Rx: Rx Indication: Alevicyn SG Antipruritic Gel is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and atopic dermatitis. Alevicyn SG Antipruritic Gel may be also used to relieve the pain of first and second degree burns. Alevicyn SG Antipruritic Gel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

OTC Indication: Alevicyn SG Antipruritic Gel is intended to relieve the burning and itching associated with many common types of skin irritation, lacerations, abrasions, and minor burns. Alevicyn SG Antipruritic Gel is also indicated for the management of irritation and pain from minor burns, including sunburn.

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.

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9 510(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: December 17, 2014

II. DEVICE

Name of Device: Alevicyn SG Antipruritic Gel
Common or Usual Name: Hydrogel Wound Dressing
Classification Name: Wound, Dressing, Drug
Regulatory Class: Unclassified, Pre-amendment status
Product Code: FRO

III. PREDICATE DEVICE

Epicyn Hydrogel manufactured by Oculus Innovative Sciences (K102945)

IV. DEVICE DESCRIPTION

The Alevicyn SG Gel is an opaque gel, slightly chlorinated odor, low viscosity spray gel. The product has a pH range of 5.5-7.0 and a viscosity target of 500-5000 cP and will be supplied in polyethylene terephthalate (PET) round-bottles with polypropylene (PP) screw-top closure and a finger pump sprayer.

V. INDICATIONS FOR USE

Rx Indication: Under the supervision of a health care professional, Alevicyn SG Antipruritic Gel is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and atopic dermatitis. Alevicyn SG Antipruritic Gel may be also used to relieve the pain of first and second degree burns. Alevicyn SG Antipruritic Gel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

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OTC Indication: Alevicyn SG Gel is intended to relieve the burning and itching associated with many common types of skin irritation, lacerations, abrasions, and minor burns. Alevicyn SG Gel is also indicated for the management of irritation and pain from minor burns, including sunburn.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Submitter/ Holder	**Proposed Device: Alevicyn SG Antipruritic Gel** Oculus Innovative Sciences	**Predicate Device: K102945 Epicyn Hydrogel** Oculus Innovative Sciences
Indications for Use	Rx Indication: Alevicyn SG Gel is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and atopic dermatitis.Alevicyn SG Gel may be also 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. OTC Indication: Alevicyn SG Gel is intended to relieve the burning and itching associated with many common types of skin irritation, lacerations, abrasions, and minor burns. Alevicyn SG Gel is also indicated for the management of irritation and pain from minor burns, including sunburn.	Epicyn hydrogel is intended indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and atopic dermatitis. The Epicyn Gel may also be used to relieve the pain of first and second degree burns. Epicyn Gel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.
Mechanism of Action	Skin barrier emollient and moisturizer	Same
Delivery System	Hydrogel	Same
Physical Characteristics	pH: 5.5-7.0 FAC: 140– 150 ppm	Same
Sterility Claim	Non-sterile	Same
Shelf Life	24 months	Same
Source	Sponsor/Manufacturer	Sponsor/Manufacturer

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VII. PERFORMANCE DATA

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

Biocompatibility Testing
The biocompatibility data provided for the Alevicyn SG Gel was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO- 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, 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. The solution is considered a breached/compromised surface device with limited contact. Biocompatibility testing completed: Cytotoxicity –Agar Diffusion Test –ISO, Direct Systemic Injection Test – ISO, Primary Ocular Irritation – ISO, Direct Contact 7 Day Cumulative Skin Irritation Study on Wounded and Intact Skin, Direct Buehler Sensitization Test – ISO.

Bench Testing
The following tests were reviewed to support the performance of Alevicyn SG Gel: package integrity, visual inspection, pH, Free Available Chlorine (FAC), and antimicrobial preservative effectiveness testing. The Alevicyn SG Gel meets specification and performance characteristics and is substantially equivalent to the predicate device.

VIII. CONCLUSION

Alevicyn SG Gel is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Epicyn Atopic Dermatitis Hydrogel manufactured by Oculus Innovative Sciences, Inc. (K102945). Therefore, the Oculus Alevicyn SG Gel is substantially equivalent to the predicate device.