



December 1, 2017

Sonoma Pharmaceuticals, Inc.
Brian Martin
Director of Regulatory Affairs and Quality Control
1129 N. McDowell Boulevard
Petaluma, California 94954

Re: K171935
Trade/Device Name: Alevicyn SG Antimicrobial Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 2, 2017
Received: November 3, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Indications for Use

510(k) Number (if known)
K171935

Device Name
Alevicyn SG Antimicrobial Gel

Indications for Use (Describe)

Rx Indications: Alevicyn SG Antimicrobial Gel is intended to moisten the wound bed and facilitate autolytic debridement of acute and chronic dermal lesions. Alevicyn SG Antimicrobial 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, seborrhea and seborrheic dermatitis, dermal irritation, sores, injuries, and ulcers of dermal tissue in addition to moistening and lubricating absorbent wound dressings. The Alevicyn SG Antimicrobial Gel may also be used to manage partial or full thickness wounds such as first and second degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), and trauma wounds. Alevicyn SG Antimicrobial Gel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

OTC Indications for Use: Alevicyn SG Antimicrobial Gel is intended for OTC use to relieve itch and pain from minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns. Hydrogel is also intended to moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement and is beneficial to wound management and the healing process.

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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“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

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

I. SUBMITTER

Sonoma Pharmaceuticals, 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: November 28, 2017

II. DEVICE

Name of Device: Alevicyn SG Antimicrobial Gel
Common or Usual Name: Wound Gel
Classification Name: Dressing, Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO

III. PREDICATE DEVICE

Alevicyn SG Antipruritic Gel (K152945) manufactured by Sonoma Pharmaceuticals, Inc.
Puracyn Plus Antimicrobial Gel (K150799), manufactured by Innovacyn, Inc.

IV. REFERENCE DEVICE

Alevicyn SG Gel (K143590) manufactured by Sonoma Pharmaceuticals, Inc.

V. DEVICE DESCRIPTION

The Alevicyn SG Antimicrobial Gel is an opaque gel, slightly chlorinated odor, low viscosity spray gel. The product will be supplied in polyethylene terephthalate (PET) round-bottles with polypropylene (PP) screw-top closure and a finger pump sprayer. Ingredients: Water, sodium lithium magnesium fluorosilicate, dimethicone, sodium phosphate, sodium bicarbonate, sodium chloride, sodium sulfate, with hypochlorous acid and sodium hypochlorite as gel preservatives.

VI. INDICATIONS FOR USE

Rx Indication: Alevicyn SG Antimicrobial Gel is intended to moisten the wound bed and facilitate autolytic debridement of acute and chronic dermal lesions. Alevicyn SG Antimicrobial 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, seborrhea and seborrheic dermatitis, dermal irritation, sores, injuries, and ulcers of dermal tissue in addition to moistening and lubricating absorbent wound dressings. The Alevicyn SG Antimicrobial Gel may also be used to manage partial or full thickness wounds such as first and second degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), and trauma wounds. Alevicyn SG Antimicrobial Gel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

OTC Indications: Alevicyn SG Antimicrobial Gel is intended for OTC use to relieve itch and pain from minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns. Hydrogel is also intended to moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement and is beneficial to wound management and the healing process.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

| Submitter/ Holder | Proposed Device: Alevicyn SG Antimicrobial Gel, Sonoma Pharmaceuticals | Predicate Device: K152945 – Rx Alevicyn SG Gel, Sonoma Pharmaceuticals | Predicate Device: K150799 Puracyn Plus Antimicrobial HydroGel | Reference Device: K143590 – OTC Alevicyn SG Gel, Sonoma Pharmaceuticals |
|---|--|---|--|--|
| Prescription Indications for Use | <p>Rx Indication: Alevicyn SG Antimicrobial Gel is intended to moisten the wound bed and facilitate autolytic debridement of acute and chronic dermal lesions. Alevicyn SG Antimicrobial 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, seborrhea and seborrheic dermatitis, dermal irritation, sores, injuries, and ulcers of dermal tissue in addition to moistening and lubricating absorbent wound dressings. The Alevicyn SG Antimicrobial Gel may also be used to manage partial or full thickness wounds such as first and second degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), and trauma wounds. Alevicyn SG Antimicrobial Gel helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.</p> | <p>Rx Indication: Under the supervision of a healthcare professional, Alevicyn SG Gel is intended 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.</p> | <p>Rx Indication: Puracyn® Plus Antimicrobial Hydrogel Professional Formula is intended for use by healthcare professionals to moisten the wound bed and facilitate autolytic debridement of acute and chronic dermal lesions, as indicated below. Puracyn® Plus Antimicrobial Hydrogel Professional Formula relieves itch and pain associated with dermal irritation, sores, injuries and ulcers of dermal tissue in addition to moistening and lubricating absorbent wound dressings. Puracyn® Plus Antimicrobial Hydrogel Professional Formula is indicated for the management of partial or full thickness wounds such as 1st and 2nd degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), trauma wounds, and various dermatoses including atopic dermatitis.</p> | <p>Rx Indication: Alevicyn SG Gel is intended to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and atopic 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.</p> |

| Submitter/ Holder | Proposed Device: Alevicyn SG Antimicrobial Gel, Sonoma Pharmaceuticals | Predicate Device: K152945 – Rx Alevicyn SG Gel, Sonoma Pharmaceuticals | Predicate Device: K150799 Puracyn Plus Antimicrobial HydroGel | Reference Device: K143590 – OTC Alevicyn SG Gel, Sonoma Pharmaceuticals |
|--------------------------------|--|---|--|--|
| OTC Indications for Use | <p>OTC Indication: Alevicyn SG Antimicrobial Gel is intended for OTC use to relieve itch and pain from minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns. Hydrogel is also intended to moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement and is beneficial to wound management and the healing process.</p> | None | <p>OTC Indication: Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel is intended for OTC use to relieve itch and pain from minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns. Hydrogel is also intended to moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement and is beneficial to wound management and the healing process.</p> | <p>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 Antipruritic Gel is also indicated for the management of irritation and pain from minor burns, including sunburn.</p> |
| Mechanism of Action | Skin emollient and moisturizer | Same | Same | Same |
| Delivery System | Bottle, Spray Gel | Same | Bottle – Twist Top | Same |
| Description | <p>Appearance: Opaque Colorless semi viscous gel Odor: Slightly Chlorinated</p> | Same | Same | Same |

| Submitter/ Holder | Proposed Device: Alevicyn SG Antimicrobial Gel, Sonoma Pharmaceuticals | Predicate Device: K152945 – Rx Alevicyn SG Gel, Sonoma Pharmaceuticals | Predicate Device: K150799 Puracyn Plus Antimicrobial HydroGel | Reference Device: K143590 – OTC Alevicyn SG Gel, Sonoma Pharmaceuticals |
|------------------------------|--|---|---|--|
| Ingredients | Water, sodium lithium magnesium fluorosilicate, dimethicone, sodium phosphate, sodium bicarbonate, sodium chloride, sodium sulfate, with hypochlorous acid and sodium hypochlorite as gel preservatives. | Same | Electrolyzed water, Lithium Magnesium, Sodium Silicate, Phosphates, Sodium Bicarbonate, Sodium Chloride, Sodium Sulfate, Hypochlorous Acid (0.01%), Sodium Hypochlorite | Same |
| Sterility Claim | Non-sterile Preserved/Conforming to USP <51> | Same | Non Sterile | Same |
| Shelf Life | 24 months | Same | 2 years | Same |

VIII. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the Alevicyn SG Antimicrobial Gel 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. The Alevicyn SG Antimicrobial Gel was evaluated for cytotoxicity, irritation, sensitization. In addition, a toxicological risk assessment was conducted to support the prolonged use of the device.

Bench Testing

The following tests were performed to support the performance of Alevicyn SG Antimicrobial Gel: visual inspection, pH, viscosity, Free Available Chlorine (FAC) and Antimicrobial Preservative Effectiveness Testing against the following bacteria in the gel while on the shelf: *Proteus mirabilis*, *Serratia marcescens*, antibiotic resistant Methicillin-Resistant *Staphylococcus aureus* (MRSA), and *Acinetobacter baumannii*. The Alevicyn SG Antimicrobial Gel meets specification and performance characteristics and is substantially equivalent to the predicate devices.

IX. CONCLUSION

Alevicyn SG Antimicrobial Gel is substantially equivalent in intended use, technological characteristics, safety and effectiveness to Alevicyn SG Gel (K152945), and Puracyn Plus Antimicrobial Gel (K150799). Therefore, the Alevicyn SG Antimicrobial Gel is substantially equivalent to the predicate devices.