



April 2, 2018

Sonoma Pharmaceuticals, Inc.
Brian Martin
VP Regulatory and Quality
1129 N. McDowell Blvd.
Petaluma, California 94954

Re: K173896
Trade/Device Name: Microcyn Antimicrobial Hydrogel
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 6, 2018
Received: March 7, 2018

Dear Brian 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,

Jennifer R. Stevenson -S3

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)

K173896

Device Name

Microcyn Antimicrobial Hydrogel

Indications for Use (Describe)

Rx: Under the supervision of a health care professional Microcyn Antimicrobial Hydrogel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Antimicrobial Hydrogel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

OTC: Microcyn Antimicrobial Hydrogel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Antimicrobial Hydrogel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

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.

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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

Sonoma Pharmaceuticals, Inc.
1129 North McDowell Blvd.
Petaluma, CA 94954

Phone: (707) 283-0550

Fax: (707) 283-0551

Contact Person: Brian W. Martin, Vice President of RA, QC, QA

Date Prepared: March 6, 2018

II. DEVICE

Name of Device: Microcyn Antimicrobial Hydrogel

Common or Usual Name: Wound Gel

Classification Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Code: FRO

III. PREDICATE DEVICE

Microcyn Plus Skin and Wound Gel manufactured by Oculus Innovative Sciences (K153648) and Alevicyn SG Antimicrobial Gel by Sonoma Pharmaceuticals, Inc., (K171935)

IV. DEVICE DESCRIPTION

The Microcyn Antimicrobial Hydrogel is a clear hydrogel, slightly chlorinated odor, viscous gel. The product has a pH range of 6.2-7.8 and a viscosity target of >1000 cP and will be supplied in polyethylene terephthalate (PET) tube-bottles with polypropylene (PP) screw-top closure.

V. INDICATIONS FOR USE**Rx Indication:**

Under the supervision of a health care professional Microcyn Antimicrobial Hydrogel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Antimicrobial Hydrogel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

OTC Indication:

Microcyn Antimicrobial Hydrogel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Antimicrobial Hydrogel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Submitter/ Holder	Proposed Device: Microcyn Antimicrobial Hydrogel, Sonoma Pharmaceuticals	Previous 510k K153648- Microcyn Plus Hydrogel- Oculus Innovative Sciences.	Predicate Device: K171935 Alevicyn SG Antimicrobial Gel, Sonoma Pharmaceuticals, Inc.
Indications for Use	<p>Rx Indication: Under the supervision of a health care professional Microcyn Antimicrobial Hydrogel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Antimicrobial Hydrogel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.</p> <p>OTC Indication: Microcyn Antimicrobial Hydrogel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Antimicrobial Hydrogel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.</p>	<p>Rx Indications for Use: Under the supervision of a health care professional Microcyn Plus Skin and Wound Gel is intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.</p> <p>OTC Indications for Use: Microcyn Plus Skin and Wound Gel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Plus Skin and Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.</p>	<p>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.</p> <p>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.</p>
Sterility Claim	Non-sterile Preserved/Conforming to USP <51>	Same	Non-sterile Preserved/Conforming to USP <51>

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Mechanism of Action	Wound moisturizer	Same	Same
Delivery System	Hydrogel	Same	Same
Ingredients	Water Sodium Lithium Magnesium Fluorosilicate Sodium Phosphate Sodium Chloride Hypochlorous Acid Sodium Hypochlorite	Same	Water, sodium lithium magnesium fluorosilicate, dimethicone, sodium phosphate, sodium bicarbonate, sodium chloride, sodium sulfate, hypochlorous acid and sodium hypochlorite

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the Microcyn Antimicrobial Hydrogel 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 gel is considered a breached/compromised surface device with limited contact.

The biocompatibility evaluation for the Microcyn Antimicrobial Hydrogel 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 Microcyn Antimicrobial Hydrogel was evaluated for cytotoxicity, systemic toxicity, irritation, and sensitization. In addition, a toxicological risk assessment was provided to support the prolonged use of the device.

Bench Testing

The following tests were performed to support the performance of Microcyn Antimicrobial Hydrogel: package integrity, visual inspection, viscosity, pH, Free Available Chlorine (FAC), Preservative Effectiveness Testing in the gel while on the shelf. Microcyn Antimicrobial Hydrogel meets specification and performance characteristics and is substantially equivalent to the predicate device.

VIII. CONCLUSION

Microcyn Antimicrobial Hydrogel is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Microcyn Plus Skin and Wound Hydrogel manufactured by Sonoma Pharmaceuticals, Inc. (K153648) and Alevicyn SG Antimicrobial Gel, K171935. Therefore, the Sonoma Pharmaceuticals, Inc. Microcyn Antimicrobial Hydrogel is substantially equivalent to the predicate devices.