



November 21, 2017

Sonoma Pharmaceuticals, Inc.
Brian Martin
VP Regulatory
1129 N. McDowell Boulevard
Petaluma, California 94954

Re: K172622

Trade/Device Name: Microcyn Antimicrobial Skin and Wound Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 29, 2017
Received: September 1, 2017

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,

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)

K172622

Device Name

Microcyn Antimicrobial Skin and Wound Cleanser

Indications for Use (Describe)

Rx Indications: Under the supervision of a healthcare professional, Microcyn Antimicrobial Skin and Wound Cleanser is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC Indications for Use: Microcyn Antimicrobial Skin and Wound Cleanser is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

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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"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: August 29, 2017

II. DEVICE

Name of Device: Microcyn Antimicrobial Skin and Wound Cleanser

Common or Usual Name: Wound Cleanser

Classification Name: Solution, Saline Wound Dressing Regulatory

Class: Unclassified, Pre-amendment status Product Code: FRO

III. PREDICATE DEVICE

Puracyn Skin and Wound Cleanser with Preservatives manufactured by Sonoma Pharmaceuticals (K090206)

Hydrocleanse Antimicrobial Skin and Wound Cleanser manufactured by Sonoma Pharmaceuticals (K171727)

IV. DEVICE DESCRIPTION

The Microcyn Antimicrobial Skin and Wound Cleanser is a clear hypotonic solution that aids in the mechanical removal of debris and foreign material from the application site. It is also for the management of skin abrasions, lacerations, irritation, cuts, and wounds.

V. INDICATIONS FOR USE**Rx Indications for Use:**

Under the supervision of a healthcare professional, Microcyn™ Antimicrobial Skin and Wound Cleanser is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

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K172622 Microcyn Antimicrobial Skin and Wound Cleanser 510(k) Summary

OTC Indications for Use:

Microcyn™ Antimicrobial Skin and Wound Cleanser is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Submitter/ Holder	Proposed Device: Microcyn Antimicrobial Skin and Wound Cleanser Sonoma Pharmaceuticals, Inc.	Predicate Device: K090206 Puracyn Skin and Wound Cleanser with Preservatives Sonoma Pharmaceuticals, Inc.	Predicate Device: K171727 Hydrocleanse Antimicrobial Skin and Wound Care Solution Sonoma Pharmaceuticals, Inc.
Indications for Use	Rx Indications: Under the supervision of a healthcare professional, Microcyn™ Antimicrobial Skin and Wound Cleanser is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds. OTC Indications: Microcyn™ Antimicrobial Skin and Wound Cleanser is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	Rx Indications: Puracyn Skin and Wound Cleanser with Preservatives is intended to be used by health care professional in the management via debridement of wounds such as stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot ulcers, post- surgical wounds, first and second degree burns, grafted and donor sites. OTC Indications: Puracyn™ Skin and Wound Cleanser with preservatives is intended for OTC use for the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	Rx Indications: Under the supervision of a healthcare professional, Hydrocleanse™ Antimicrobial Skin and Wound Care Solution is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post- surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices to irrigate wounds. OTC Indications: For management of minor skin abrasions, minor lacerations, minor irritations, minor cuts, minor burns and intact skin.
Technology	Ingredients: Water, sodium chloride, hypochlorous acid, sodium hypochlorite	Ingredients: Water, sodium chloride, hypochlorous acid, sodium hypochlorite	Ingredients: Water, sodium sulfate, monobasic sodium phosphate, sodium chloride, hypochlorous acid, sodium hypochlorite
Sterility Claim	Non-sterile	Same	Same
Mechanism of Action	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the wound or device.	Same	Same
Delivery System	Aqueous Solution	Same	Same

Sonoma Pharmaceuticals, Inc.

K172622 Microcyn Antimicrobial Skin and Wound Cleanser 510(k) Summary

Shelf Life	24 months	Same	12 months
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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 Skin and Wound Cleanser 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.

Bench Testing

The following tests were performed to support the performance of Microcyn Antimicrobial Wound Care Solution: package integrity, visual inspection, osmolality, pH, Free Available Chlorine (FAC). USP <51> testing was used to support preservative effectiveness of the product with the compendia organisms: *P. aeruginosa* (ATCC 9027), *E. coli* (ATCC 8739), *S. aureus* (ATCC 6538), *C. albicans* (ATCC 10231), *A. niger* (ATCC 16404) - and the following bacteria in solution: *S. epidermidis* (ATCC 12228), *P. acnes* (ATCC 6919), *Proteus mirabilis* (ATCC- 29906), *S. marcescens* (ATCC-13880), antibiotic resistant Methicillin-Resistant *S. aureus* (MRSA) (ATCC-BAA-1708), Vancomycin- resistant *E. faecalis* (VRE) (ATCC-BAA2320), and *A.baumannii* (ATCC 19606).

VIII. CONCLUSION

Microcyn Antimicrobial Skin and Wound Cleanser is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Puracyn Skin and Wound Cleanser with Preservatives manufactured by Sonoma Pharmaceuticals, Inc. (K090206) and Hydrocleanse Antimicrobial Skin and Wound Care Solution manufactured by Sonoma Pharmaceuticals (K171727). Therefore, the Microcyn Antimicrobial Skin and Wound Cleanser is substantially equivalent to the predicate devices.