November 8, 2024

Sonoma Pharmaceuticals, Inc.
Everardo Garibay Ramirez
General Manager
1129 North McDowell Blvd.
Petaluma, California 94954

Re: K240510
Trade/Device Name: Microdacyn Hydrogel
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 10, 2024
Received: October 11, 2024

Dear Everardo Garibay Ramirez:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240510

Device Name
Microdacyn Hydrogel

Indications for Use *(Describe)*
Rx INDICATIONS: Under the supervision of a healthcare professional, Microdacyn Hydrogel is intended for management of wounds associated with dermal irritation, sores, injuries and ulcers of dermal tissue. Microdacyn Hydrogel is intended for use on first and second degree burns, exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically debrided wounds.

OTC INDICATIONS: Microdacyn Hydrogel is intended for use on minor skin irritations, lacerations, abrasions and minor burns. Microdacyn Hydrogel is also indicated for the management of irritation from minor 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.

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 performance information in accordance with 21 CFR 807.92.

I. SUBMITTER

Submitted by:
Sonoma Pharmaceuticals, Inc.
1129 North McDowell Blvd.
Petaluma CA, 94954.
Phone: (707) 9710128
Establishment Registration: 3004554409.

Manufacturer:
Oculus Technologies of Mexico, S.A. de C.V.
Industria Vidriera No.81,
Fraccionamiento Industrial Zapopan Norte,
Zapopan, Jalisco, MX 45130.
Phone: (+52) 33 1605 6543/ (+52) 33 3833-6722.
Establishment Registration Number: 3007244484.

Owner/Operator:
Sonoma Pharmaceuticals, Inc.
1129 North McDowell Blvd.
Petaluma CA, 94954.
Owner/Operator Number: 9063175.

Contact Person: Everardo Garibay Ramírez, General Manager.
Date Prepared: October 16th, 2024.

II. DEVICE

Name of Device: Microdacyn Hydrogel.
Common or Usual Name: Hydrogel Wound Dressing.
Classification Name: Dressing, wound, drug.
Class: Unclassified.
Product Code: FRO.
510(k) Review Panel: General & Plastic Surgery.

III. PREDICATE DEVICE

Microcyn Skin and Wound HydroGel (K093585) manufactured for Sonoma Pharmaceuticals.

IV. DEVICE DESCRIPTION

Microdacyn Hydrogel is a non-sterile, aqueous hydrogel that contains sodium hypochlorite and hypochlorous acid as preservatives to prevent the growth of microorganisms within the container during shelf-life.

V. INDICATIONS FOR USE

Rx Indications for Use: Under the supervision of a healthcare professional, Microdacyn Hydrogel is intended for management of wounds associated with dermal irritation, sores, injuries and ulcers of dermal tissue. Microdacyn Hydrogel is intended for use on first and second degree burns, exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically debrided wounds.

OTC Indications for Use: Microdacyn Hydrogel is intended for use on minor skin irritations, lacerations, abrasions and minor burns. Microdacyn Hydrogel is also indicated for the management of irritation from minor sunburn.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1. Summary of comparison of technological characteristics.

Characteristic	Proposed Device: Microdacyn Hydrogel (K240510)	Predicate Device: Microcyn Skin and Wound HydroGel (K093585)
Indications for Use	**Rx Indications for Use:** Under the supervision of a healthcare professional, Microdacyn Hydrogel is intended for management of wounds associated with dermal irritation, sores, injuries and ulcers of dermal tissue. Microdacyn Hydrogel is intended for use on first and second degree burns, exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically debrided wounds. **OTC Indications for Use:** Microdacyn Hydrogel is intended for use on minor skin irritations, lacerations, abrasions and minor burns. Microdacyn Hydrogel is also indicated for the management of irritation from minor sunburn.	**Rx Indications for Use:** Under the supervision of a healthcare professional, Microcyn Skin and Wound HydroGel is intended for management of wounds including itch and pain relief associated with dermal irritation, sores, injuries and ulcers of dermal tissue. Microcyn Skin and Wound HydroGel is intended for use on first and second degree burns, exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically debrided wounds. **OTC Indications for Use:** Microcyn Skin and Wound HydroGel is intended for use to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns. Microcyn is also indicated for the management of irritation and pain from minor sunburn.
Where Used	RX Only; OTC	Same
Delivery System	Hydrogel	Same
Mechanism of Action	The mode of action is achieved through the following: – Maintaining a moist wound environment.	Same
Composition	– Water (96.524%) – Sodium Magnesium Fluorosilicate (3.000%) – Sodium Phosphate (0.400%) – Sodium Chloride (0.066%) – Hypochlorous acid (0.008%) – Sodium Hypochlorite (0.002%)	Same

Characteristic	Proposed Device: Microdacyn Hydrogel (K240510)	Predicate Device: Microcyn Skin and Wound HydroGel (K093585)
Sterilization	Non-sterile	Same
Shelf Life	24 months	18 months
Specification	Viscosity: 12,000-20,000 cP.	Same
Container closure system	50 mL, 100 mL and 200 mL polyethylene terephthalate (PET) bottles with a polypropylene (PP) Snap-top screw cap and lift 'n' peel liner.	2oz polyethylene terephthalate (PET) bottles with a polypropylene (PP) Snap-top screw cap and lift 'n' peel liner.

VII. PERFORMANCE DATA

Biocompatibility Testing

- ISO-10993-1 Biological Evaluation of Medical Devices.

Performance Testing

- USP Antimicrobial Effectiveness Testing <51>.

VIII. CONCLUSION

Microdacyn Hydrogel has the same intended use, technological characteristics and the performance and biocompatibility testing demonstrate that the device is as safe and effective as the Microcyn Skin and Wound HydroGel (K093585) manufactured for Sonoma Pharmaceuticals, Inc. Therefore, Microdacyn Hydrogel is substantially equivalent to the predicate device.