June 24, 2026

Sonoma Pharmaceuticals, Inc.
Arturo Angel
Vice President of Product Development
5445 Conestoga Ct. Suite 150
Boulder, Colorado 80301

Re: K261023
Trade/Device Name: Microdacyn Wound Irrigation Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 27, 2026
Received: March 30, 2026

Dear Arturo Angel:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MUSTAFA A. MAZHER -S

For Yu-Chieh Chiu PhD,
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)*
K261023

Device Name
Microdacyn Wound Irrigation Solution

Indications for Use *(Describe)*

Rx Indications for Use:
Under the supervision of healthcare professionals, Microdacyn Wound Irrigation Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/or dirty wounds, acute and chronic dermal lesions, such as Stage I–IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and partial thickness second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.

OTC Indications for Use:
Microdacyn Wound Irrigation Solution is intended for OTC management of minor skin abrasions, minor lacerations, minor irritations and intact skin of the face, eyelid and eyelashes.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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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."

K261023

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.
5445 Conestoga Ct Ste 150,
Boulder CO, 80301.
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.
5445 Conestoga Ct Ste 150,
Boulder CO, 80301.
Owner/Operator Number: 9063175.

Contact Person: Arturo J. Angel, *Vice President of Product Development.*
Date Prepared: June 23rd, 2026.

II. DEVICE

Name of Device: Microdacyn Wound Irrigation Solution (K261023)
Common or Usual Name: Wound Cleanser.
Classification Name: Solution, Saline Wound Dressing.
Class: Unclassified.
Product Code: FRO
510(k) Review Panel: General & Plastic Surgery

III. PREDICATE DEVICES

Primary predicate device: Microdacyn Wound Care Solution (K233399) manufactured for Sonoma Pharmaceuticals, Inc.

Secondary predicate device: Granudacyn® Wound Irrigation Solution (K243415) manufactured for P.G.F. Industry Solutions GmbH.

IV. DEVICE DESCRIPTION

Microdacyn Wound Irrigation Solution (K261023) is a clear solution that aids in the mechanical removal of debris and foreign material from the application site. The solution contains hypochlorous acid as a preservative to inhibit microbial contamination during shelf storage.

V. INDICATIONS FOR USE

Rx Indications for Use:

Under the supervision of healthcare professionals, Microdacyn Wound Irrigation Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/or dirty wounds, acute and chronic dermal lesions, such as Stage I–IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and partial thickness second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.

OTC Indications for Use:

Microdacyn Wound Irrigation Solution is intended for OTC management of minor skin abrasions, minor lacerations, minor irritations and intact skin of the face, eyelid and eyelashes.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1. Summary of comparison of technological characteristics.

Characteristic	Proposed Device: Microdacyn Wound Irrigation Solution (K261023)	Primary Predicate Device: Microdacyn Wound Care Solution (K233399)	Secondary Predicate Device: Granudacyn® Wound Irrigation Solution (K243415)
Indications for Use	**Rx Indications for Use:** Under the supervision of healthcare professionals, Microdacyn Wound Irrigation Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/or dirty wounds, acute and chronic dermal lesions, such as Stage I–IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and partial thickness second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings. **OTC Indications for Use** Microdacyn Wound Irrigation Solution is intended for OTC management of minor skin abrasions, minor lacerations, minor irritations and intact skin of the face, eyelid and eyelashes.	**Rx Indications for Use:** Under the supervision of a healthcare professional, Microdacyn 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 intended to irrigate wounds. **OTC Indications for Use:** Microdacyn Wound Care Solution is intended for OTC management of minor skin abrasions, minor lacerations, minor irritations and intact skin of the face, eyelid and eyelashes.	**Rx Indications for Use:** Under the supervision of healthcare professionals, Granudacyn Wound Wash Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/or dirty wounds, acute and chronic dermal lesions, such as 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 and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.
Where Used	RX Only; OTC	RX Only; OTC	RX Only
Delivery System	Aqueous solution presented in pour bottle, spray bottle configurations.	Aqueous solution presented in spray bottle configurations.	Aqueous solution presented in squeeze bottle, spray nozzle, and instillation bottle configurations.

Characteristic	Proposed Device: Microdacyn Wound Irrigation Solution (K261023)	Primary Predicate Device: Microdacyn Wound Care Solution (K233399)	Secondary Predicate Device: Granudacyn® Wound Irrigation Solution (K243415)
Mechanism of Action	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the skin or wound.	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the skin or wound.	Mechanical removal of wound debris.
Preservative	Hypochlorous acid (0.003%)	Hypochlorous acid (0.003%)	Hypochlorous acid.
Use Case	Single patient, multiple use.	Single use.	Single patient, multi-use.
Sterilization	Non-sterile	Non-sterile	Non-sterile
Shelf Life	24 months	24 months	28 months
Size and Configuration of the Container-Closure System	– 4 oz, 8 oz, 16 oz, and 34 oz: provided in polyethylene terephthalate (PET) bottles with polypropylene (PP) flip-top cap and Lift 'n' Peel liner. – 2 oz, 4 oz, 8 oz, 8.5 oz, and 16 oz: provided in polyethylene terephthalate (PET) bottles with polypropylene (PP) sprayer / spray gun.	PET bottles with a PP sprayer or PP spray gun (available in 2 oz, 8 oz, 8.5 oz, and 16 oz).	Squeeze bottle, spray nozzle, instillation bottle offered (available in 250ml, 500ml,1000ml).

VII. NON-CLINICAL DATA

Biocompatibility Testing

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

Performance Testing

- USP <51>Antimicrobial Effectiveness Test.

VIII. CONCLUSION

Microdacyn Wound Irrigation Solution (K261023) is substantially equivalent in intended use, technological characteristics, and is as safe, as effective, as the legally marketed predicate devices Microdacyn Wound Care Solution (K233399) manufactured for Sonoma Pharmaceuticals, Inc. and Granudacyn® Wound Irrigation Solution (K243415) manufactured for P.G.F. Industry Solutions GmbH.