



January 12, 2026

SiOxMed, LLC  
% Jennifer Daudelin  
Director, MedTech Regulatory Affairs  
ProPharma  
107 West Hargett St.  
Raleigh, North Carolina 27601

Re: K250890  
Trade/Device Name: SBC1 Cream  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: January 2, 2026  
Received: January 2, 2026

Dear Jennifer Daudelin:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**MUSTAFA A. MAZHER -S**

For 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

## Indications for Use

510(k) Number (if known)

K250890

Device Name

SBC1 Cream

Indications for Use (Describe)

The SBC1 Cream is a skin emulsion indicated for management of pruritus and dryness of skin in atopic dermatitis and allergic contact dermatitis. Not to be used on breached or compromised skin or open sores.

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 [AS REQUIRED BY 21 CFR 807.92]

**Sponsor:** SiOxMed, LLC  
2452 Salem Park Drive  
Winston Salem, NC 27127  
(336) 551-2209

**Contact:** Jennifer A. Daudelin, M.S.J.  
ProPharma MedTech  
107 West Hargett St.  
Raleigh, NC 27601  
Ph: 347-954-0395  
Email: jennifer.daudelin@propharmagroup.com

**Date Prepared:** January 6, 2026

**Proposed Class:** Unclassified

**Trade Name:** SBC1 Cream

**Common Name:** Cream

**Product Codes:** FRO

**Predicate Device(s):**

510(k) Number	Manufacturer	Device Name	Procode	Class
K242406	SiOxMed, LLC	SiOxC Cream	FRO	Unclassified

### Indications for Use

The SBC1 Cream is a skin emulsion indicated for management of pruritus and dryness of skin in atopic dermatitis and allergic contact dermatitis. Not to be used on breached or compromised skin or open sores.

### Device Description

SBC1 Cream is a fragrance free, preserved, non-sterile, topical skin emulsion indicated for management of pruritus and dryness of skin in atopic dermatitis and allergic contact dermatitis. SBC1 Cream supports a moist environment. SBC1 Cream is provided prescription only in various sizes for single patient use.

### Comparison of Technological Characteristics

The SBC1 Cream has the same indications for use and similar formulation and ingredients as compared with the predicate device. The bench testing demonstrates that the performance characteristics of the SBC1 Cream are equivalent to the legally marketed predicate, and therefore

supports a determination of Substantial Equivalence for the proposed indications for use.

The table below compares the SBC1 characteristics to the predicate device.

<b>Product Characteristic</b>	<b>Subject Device SBC1 Cream</b>	<b>Predicate Device SiOxC Cream</b>
<b>510(k) Number</b>	K250890	K242406
<b>Regulation</b>	Unclassified	Unclassified
<b>Product Code</b>	FRO	FRO
<b>Indications for Use</b>	SBC1 Cream is a skin emulsion indicated for management of pruritus and dryness of skin in atopic dermatitis and allergic contact dermatitis. Not to be used on Breached or Compromised skin or open sores.	SiOxC Cream is a skin emulsion indicated for management of pruritus and dryness of skin in atopic dermatitis and allergic contact dermatitis. Not to be used on Breached or Compromised skin or open sores.
<b>Principle of Operation</b>	Promotes a moist environment	Promotes a moist environment
<b>Composition</b>	A water-based formulation containing emollients, humectants, structural and stabilizing agents, pH adjusters, surfactants/emulsifiers, antioxidants, and preservatives. The formulation includes a proprietary amorphous hydrated silica.	A water-based formulation containing emollients, humectants, structural and stabilizing agents, pH adjusters, surfactants/emulsifiers, antioxidants, and preservatives. The formulation includes a proprietary amorphous hydrated silica.
<b>Preservative</b>	Phenoxyethanol	Phenoxyethanol
<b>Available offerings</b>	1oz and 8oz jar	1oz and 8oz jar
<b>Application</b>	2 times per day	2 times per day or as needed
<b>Single Patient Use</b>	Yes	Yes
<b>Sterility</b>	Non-sterile	Non-sterile
<b>Biocompatibility</b>	Biocompatible	Biocompatible

## **Performance Data – Non-Clinical**

### Biocompatibility

The SBC1 Cream was found to be biocompatible in accordance with ISO 10993-1 for its intended use when tested in compliance with ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 10993-23.

### Performance Testing

USP preservative effectiveness testing demonstrates the chosen preservative is performing as intended and appropriate for product formulation. Verification testing of the subject device was conducted to confirm that the modifications did not adversely affect device performance. Testing

includes the following:

Testing Parameter	Results
Color / Visual appearance	Per specification
Odor / Scent characteristics	Per specification
Formula Appearance	Per specification
Product / Package Compatibility	Per specification
Package Appearance	Per specification
pH	Per specification
Viscosity	Per specification

#### Preservative testing

Preservative Challenge Testing	Standard	Results
Preservative Effectiveness	Per USP <61>/<62>	PASS

#### Bioburden / Microbial testing

Testing Parameter	Standard	Specifications	Results
Total Plate Count (APC)	USP <61>/<62>	<100 cfu/g	PASS
Yeast & Mold (Sab Dextrose)	USP <61>/<62>	<100 cfu/g	PASS

#### **Conclusions**

Based on the similarities of the intended use / indications for use, technological characteristics and results of non-clinical performance testing, the subject device, SBC1 Cream, is substantially equivalent to the predicate device, SiOxC Cream, K242406.