August 1, 2025

SiOxMed, LLC
Adam Jorgensen
Chief Science Officer
2542 Salem Park Dr
Winston-Salem, North Carolina 27127

Re: K242406
Trade/Device Name: SiOxC Cream
Regulatory Class: Unclassified
Product Code: FRO

Dear Adam Jorgensen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 13, 2025. Specifically, FDA is updating this SE Letter to correct the Indications for Use Statement as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, OHT4: Office of Surgical and Infection Control Devices, 301-796-6196, Yu-Chieh.Chiu@fda.hhs.gov.

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

March 13, 2025

SiOxMed, LLC
% Justin Gracyalny
Regulatory Affairs Program Manager
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K242406
Trade/Device Name: SiOxC Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 14, 2024
Received: August 14, 2024

Dear Justin Gracyalny:

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

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.

Submission Number *(if known)*

K242406

Device Name

SiOxC Cream

Indications for Use *(Describe)*

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.

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.

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510(k) SUMMARY:
SiOxMed SiOxC Cream

Date Prepared	March 13, 2025
Sponsor	SiOxMed 2452 Salem Park Dr. Winston-Salem, NC 27127 (336) 551-2209
510(k) Contact	SiOxMed Adam Jorgensen, MD, PhD 2452 Salem Park Dr. Winston Salem, NC, 27127 (336) 551-2209 Regulatory@SiOxMed.com
Trade Name	SiOxC Cream
Common Name	Cream
Code – Classification	FRO Unclassified
Predicate Device	K052643 Ceragenix Corporation EPICERAM® Skin Barrier Emulsion
Reference Device	K241660 SiOxMed LLC SiOxD Wound Matrix
Device Description	SiOxC Cream is a fragrance free, preservative protected, non-sterile, topical cream intended for management of dry skin. SiOxC Cream supports a moist environment. SiOxC Cream is provided prescription only in various sizes for single patient use.
Indications for Use Statement	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.

Comparison of Technological Characteristics

The subject device is intended for use for management of dry skin. As such, this difference does not represent a new intended use.

There are no significant technological differences between the subject and predicate devices. Both devices are intended for similar uses and have similar technological characteristics including promoting a moist environment as the principle of operation, application frequency, and sterility. Both the subject and predicate device utilize the same preservative. Any minor differences such as specific cream formulation and size offerings are addressed via biocompatibility and non-clinical performance testing.

Characteristic	Subject Device SiOxMed LLC SiOxC Cream K242406	Primary Predicate Oculus Innovative Sciences, Inc. EPICERAM® Skin Barrier Emulsion K052643
Regulation	Unclassified	Unclassified
Product Classification	FRO	FRO
Common Name	Cream	Cream
Principle of Operation	Promotes a moist environment	Promotes a moist environment
Composition	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 with emollients, humectants, lipid-replenishing agents, stabilizers, pH adjusters, surfactants/emulsifiers, antioxidants, and preservatives. The formulation includes a proprietary lipid delivery system.
Preservative	Phenoxyethanol (0.5% ± 1%)	Phenoxyethanol
Available Offerings	1 or 8 fl oz jar	90g tube or 225g airless pump
Reapplication	Twice daily, as needed	Twice daily, as needed
Sterility	Non-Sterile	Non-Sterile
Biocompatibility	Biocompatible	Biocompatible

Summary of Performance Testing

Non-clinical performance testing for the SiOxC Cream included characterization of pH, viscosity, and macroscopic and microscopic appearance. Preservative effectiveness testing per USP <51> was also conducted to support the subject device shelf-life.

The SiOxC 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, and ISO 10993-23.

A Human Repeat Insult Patch Test (HRIPT) was also performed to determine the potential of the test material to elicit dermal irritation and/or induce sensitization following repeated patch applications in human subjects. The Induction Phase of the study is designed to assess the potential of the subject device to elicit an irritation reaction, whereas the Challenge Phase of the study is designed to assess the potential of the subject device to elicit a sensitization response.

120 male and female subjects ranging from 18 to 70 years old were enrolled in the study. Of the subjects who completed the Induction Phase, 100% were categorized as “No visible skin reaction” at any time point. Of the subjects who completed the Challenge Phase, 100% were categorized as “No visible skin reaction” at any time point. No re-challenge testing was required for any subjects.

Based on the test population of 106 subjects who completed the study, SiOxC Cream did not demonstrate a potential for eliciting dermal irritation or inducing sensitization.

Conclusions

Based on the similarities of the intended use / indications for use, technological and functional characteristics, and the results of the biocompatibility / non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.