July 5, 2024

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

Re: K241660
Trade/Device Name: SiOxD® Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 10, 2024
Received: June 10, 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.

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, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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)*

K241660

Device Name

SiOxD® Wound Matrix

Indications for Use *(Describe)*

The SiOxD® Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, first degree and partial thickness burns, skin tears) and draining wounds.

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.

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510(k) SUMMARY:
SiOxMed SiOxD Wound Matrix

Date Prepared	June 7, 2024
Sponsor	SiOxMed 2011 Muddy Creek Road Clemmons, NC 27012 (336) 497-1015
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	SiOxD Wound Matrix
Common Name	Wound Dressing
Code – Classification	FRO Unclassified
Predicate Device	K222189, K232847 SiOxMed LLC SiOxD Wound Matrix
Device Description	The SiOxD Wound Matrix is a non-pyrogenic, sterile, single use device intended for use in local management of wounds. The SiOxD Wound Matrix is a soft, white, conformable, non-woven, absorbent, biocompatible fiber matrix made from synthetic biomaterials. The SiOxD Wound Matrix conforms in the defect space / wound bed and includes a fibrous, porous structure that allows for fluid absorption. The SiOxD Wound Matrix is structurally similar to collagen, a key component of the native extracellular matrix, and serves as a scaffold for cellular infiltration and vascularization. SiOxD Wound Matrix promotes a moist environment for the body's natural healing process. The SiOxD Wound Matrix is not designed to be held in place with compression bandages or tapes. Only light pressure without mechanical compression or secondary bandaging is required for proper device function. The matrix applied to the wound bed naturally sloughs off during wound healing and does not require manual removal.
Indications for Use Statement	The SiOxD Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, first degree and partial thickness burns, skin tears) and draining wounds.

Comparison of Technological Characteristics

Characteristic	Subject Device SiOxMed SiOxD Wound Matrix	Primary Predicate SiOxMed SiOxD Wound Matrix K222189 / K232847
Regulation	Unclassified	Unclassified
Product Classification	FRO	FRO
Common Name	Wound Dressing	Wound Dressing
Indications for Use	The SiOxD Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, first degree and partial thickness burns, skin tears) and draining wounds.	The SiOxD Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, first degree and partial thickness burns, skin tears) and draining wounds.
Composition of Material	Hydrated amorphous silica in fibrous form	Hydrated amorphous silica in fibrous form
Primary Function	Wound dressing	Wound dressing
Available Sizes	4.91 – 16 in^2, 0.1 – 1.0g • 2.5” Round (0.1g) • 2.5” Round (0.3g) • 2.5” Round (0.7g) • 2.5” Round (1.0g) • 4” x 4” Square (1.0g)	4.91 – 16 in^2, 0.1 – 1.0g • 2.5” Round (0.1g) • 2.5” Round (0.3g) • 2.5” Round (0.7g) • 2.5” Round (1.0g) • 4” x 4” Square (1.0g)
Packaging	Single and Dual Sterile Barrier Configurations	Single and Dual Sterile Barrier Configurations
Resorbable	No	No
Absorbent	Yes	Yes
Requires Mechanical Pressure / Secondary Dressing	A non-adherent secondary wound dressing (e.g., multi-layer compression bandage system, or other appropriate dressing) can be placed over SiOxD Wound Matrix but is not required. Only light, brief compression is required.	A non-adherent secondary wound dressing (e.g., multi-layer compression bandage system, or other appropriate dressing) can be placed over SiOxD Wound Matrix but is not required. Only light, brief compression is required.
Moist Wound Environment	Maintains a moist wound environment	Maintains a moist wound environment
Reapplication	As needed	As needed
Customizable	Yes, trim to size	Yes, trim to size

Characteristic	Subject Device SiOxMed SiOxD Wound Matrix	Primary Predicate SiOxMed SiOxD Wound Matrix K222189 / K232847
Single Use	Yes	Yes
Non-Pyrogenic	Yes	Yes
Sterility	Gamma, 10^{-6} SAL	Gamma, 10^{-6} SAL
Biocompatibility	Biocompatible	Biocompatible

Technological Characteristics

There are no significant technological differences between the subject and predicate devices. The subject device is a line extension to the device originally cleared in K222189 / K232847. There are no differences in intended use, device sizes, material of construction, sterilization, or packaging. The subject device allows for use of alternate water raw materials in the manufacture of the subject device fiber matrix. Material testing of key physical and chemical properties demonstrated that devices manufactured with any of qualified water raw material met predetermined release criteria. A worst-case assessment of endotoxin levels showed that devices manufactured with all water raw materials meet the 20 EU/Device acceptance criteria.

Conclusions

Based on the similarities of the intended use / indications for use, technological and functional characteristics, and the results of the sterilization / packaging testing, the subject device is substantially equivalent to the legally marketed predicate device.