November 18, 2022

SiOxMed, LLC.
% Linda Braddon
Woodstock
Secure BioMed Evalutations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K222189
Trade/Device Name: SiOxD Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 18, 2022
Received: October 19, 2022

Dear Linda Braddon:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222189

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	November 17, 2022
Sponsor	SiOxMed 2011 Muddy Creek Road Clemmons, NC 27012 (336) 242-4498
510(k) Contact	Secure BioMed Evaluations 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: Class II
Primary Predicate	K161067 Engineered Tissue Solutions, LLC Mirragen™ Advanced Wound Matrix
Additional Predicate Device	K142363 Beeken Biomedical NuStat HemoStatic Dressing
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 Engineered Tissue Solutions, LLC Mirragen™ Advanced Wound Matrix K161067	Additional Predicate Beeken Biomedical NuStat XR HemoStatic Dressing K142363
Regulation	Unclassified	Unclassified	Unclassified
Product Classification	FRO	FRO	FRO
Common Name	Wound Dressing	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 Mirragen™ Advanced 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 and second degree burns, skin tears) and draining wounds.	NuStat XR is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions and incisions.
Composition of Material	Hydrated amorphous silica in fibrous form	Borate glass fibers and particulate	Knitted cellulose and continuous filament silica Cellulose (rayon, edge sealant) Optional Radiopaque element – Polypropylene thread coated with barium sulfate
Primary Function	Wound dressing	Wound dressing	Wound dressing

Characteristic	Subject Device SiOxMed SiOxD Wound Matrix	Primary Predicate Engineered Tissue Solutions, LLC Mirragen™ Advanced Wound Matrix K161067	Additional Predicate Beeken Biomedical NuStat XR HemoStatic Dressing K142363
Available Sizes	• 2.5" Round • 4" x 4" Square	• 1" x 6" • 2" x 2" • 4" x 4"	Sizes ranges from 2" to 8" in width and 2" to 60" in length
Resorbable	No	Yes	No
Absorbent	Yes	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.	To be used with non-adherent secondary bandaging	To be used with mechanical pressure
Moist Wound Environment	Maintains a moist wound environment	Maintains a moist wound environment	Not stated
Reapplication	As needed	Every 3 to 7 days as needed	As needed
Customizable	Yes, trim to size	Yes, trim to size	Yes, trim to size
Single Use	Yes	Yes	Yes
Non-Pyrogenic	Yes	Yes	Yes
Sterility	Gamma, 10^{-6} SAL	Gamma, 10^{-6} SAL	Gamma, 10^{-6} SAL
Biocompatibility	Biocompatible	Biocompatible	Biocompatible

Technological Characteristics

There are no significant technological differences between the subject and predicate devices. The subject device uses similar materials, is of a similar size, has similar design properties, and has the same intended use as the primary and additional predicates. Technological differences include that the subject device does not require mechanical pressure or secondary bandaging for proper function which is required by the predicate devices. The subject device also naturally sloughs off during healing while the primary predicate is resorbed. These differences are adequately addressed through the non-clinical performance and animal testing provided which demonstrate that they do not raise new concerns for safety or effectiveness.

Subject Device Testing Summary

Non-clinical performance testing for the SiOxD Wound Matrix include:

Test	Test Method Summary	Results
Absorption Capacity	The absorption capacity of the device was characterized.	Device was characterized as absorbent.
Partial Thromboplastin Time	ASTM F2382 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)	Clotting time was lower than control.
Complement Activation	ISO 10993-4 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	Device was characterized as a complement activator.
Fourier Transform Infrared Spectroscopy (FTIR) Analysis	FTIR spectra collected using attenuated total reflectance (ATR) were used for the purpose of characterizing the material.	Results were consistent with hydrated amorphous silica in fibrous form.
X-Ray Diffraction (XRD) Spectrometry	XRD spectrometry was used to characterize the material.	Results were consistent with hydrated amorphous silica in fibrous form.
Scanning Electron Microscope (SEM) Imaging	SEM imaging was collected to characterize the matrix structure.	The matrix structure was structurally similar to collagen and created a scaffold for cellular infiltration and vascularization.

A full thickness porcine wound healing study found equivalent wound healing performance for the SiOxD Wound Matrix when compared to the additional predicate device and untreated control sites.

The SiOxD Wound Matrix was found to be biocompatible for its intended use when tested in compliance with ISO 10993-1.

Test	Test Method Summary	Results
Cytotoxicity	ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic
Sensitization	ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin sensitization Also addressed via Human Repeat Insult Patch Testing	Non-sensitizing
Irritation	ISO 10993-23 Biological evaluation of medical devices — Part 23: Tests for irritation Also addressed via Human Repeat Insult Patch Testing	Non-irritating
Acute Systemic Toxicity	ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Non-toxic

Test	Test Method Summary	Results
Material Mediated Pyrogenicity	USP <151> Pyrogen Test	Non-pyrogenic
Subacute Systemic Toxicity	ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Non-toxic
Implantation	ISO 10993-6 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation Testing via full thickness porcine wound model; Endpoints also addressed as part of subacute toxicity testing results	No adverse tissue response.
Endotoxin	USP <85> Bacterial Endotoxins	<20EU/Device; Non-pyrogenic

A Human Repeat Insult Patch Test (HRIPT) was 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 114 subjects who completed the study, SiOxD Wound Matrix did not demonstrate a potential for eliciting dermal irritation or inducing sensitization.

All testing passed showing the device to be biocompatible for its intended use.

Conclusions

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