May 2, 2023

Organogenesis Inc.
Christina Nichols
Program Manager, Regulatory Affairs
150 Dan Rd
Canton, Massachusetts 02021

Re: K212579
Trade/Device Name: FortiShield (Biosynthetic Wound Matrix)
Regulatory Class: Unclassified
Product Code: KGN
Dated: November 22, 2022
Received: November 22, 2022

Dear Christina Nichols:

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,

David Krause -S

for 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)*
K212579

Device Name
FortiShield™ Biosynthetic Wound Matrix

Indications for Use *(Describe)*
FortiShield is indicated for: partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K212579 - FortiShield™ (Biosynthetic Wound Matrix)

Date Prepared:

May 2, 2023

Submitted By:

Organogenesis Inc.
150 Dan Rd
Canton, MA 02021

Contact:

Name: Christina Nichols
Title: Associate Director of Regulatory Affairs
Telephone: (781) 577-6065
Email: CNichols@organo.com

Device:

Trade Name:	FortiShield™ (Biosynthetic Wound Matrix)
Common Name:	Wound Dressing
FDA Product Code:	KGN
Classification Name:	Dressing, wound, collagen
510(k) Number:	K212579

Predicate Devices:

The device is substantially equivalent to the following predicate devices:

Primary Predicate:	AWBAT (K082869)
Other Predicates:	Biobrane II (K901369) and PermeaDerm B (K153678)

Device Description:

FortiShield is a sterile, translucent biosynthetic wound matrix made from a knitted tri-filament nylon fabric that is mechanically bonded to a semi-permeable silicone membrane. Denatured porcine dermal collagen is bonded to the nylon/silicone bi-layer membrane to provide a

dressing that is designed to adhere to the application site, provide a barrier to the external environment, and allow for excess exudate drainage.

FortiShield is not made with natural rubber latex. FortiShield is non-pyrogenic.

Intended Use:

FortiShield is intended for use as a temporary wound covering, and to provide a moist wound healing environment on cleanly debrided wounds after hemostasis has been established.

Indications for Use:

FortiShield is indicated for: partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears) and draining wounds.

Technological Characteristics and Performance Data (Predicate Comparison):

The device has equivalent design, intended use, material performance, and biocompatibility compared to the predicate devices.

The device has equivalent non-clinical performance as the predicate devices. Tensile elongation, water vapor transmission rate, and fatigue properties have been demonstrated as equivalent between the subject and the AWBAT predicate device.

A comparison of technological characteristics and performance data to the predicate devices is provided in **Table 1**, below.

Table 1: Comparison to Predicate Devices

Characteristic	Subject Device	Predicate Devices			Comparison
	Organogenesis Inc. **FortiShield™**	**Aubrey, Inc.** **AWBAT-S, AWBAT-D, AWBAT-M** **(Primary Predicate)**	**Sterling Drug, Inc.** **Biobrane II** **(Other Predicate)**	**PermeaDerm, Inc.** **Permeaderm B and Permeaderm CW** **(Other Predicate)**	
510(k)	K212579	K082869	K901369	K153678	N/A
FDA Product Code	KGN	KGN	FRO	FRO	The FDA product code is identical to the primary predicate.
Principles of Operation	Device covers the wound to provide a moist wound environment and allows the passage of exudate.	Devices covers the wound to provide a moist wound environment and allows the passage of exudate.	Devices covers the wound to provide a moist wound environment and allows the passage of exudate.	Devices covers the wound to provide a moist wound environment and allows the passage of exudate.	Equivalent to predicate devices.

Characteristic	Subject Device	Predicate Devices			Comparison
	Organogenesis Inc. **FortiShield™**	**Aubrey, Inc.** **AWBAT-S, AWBAT-D, AWBAT-M** **(Primary Predicate)**	**Sterling Drug, Inc.** **Biobrane II** **(Other Predicate)**	**PermeaDerm, Inc.** **Permeaderm B and Permeaderm CW** **(Other Predicate)**	
Materials and Structure	Porous Silicone and Nylon Knit Bi-layer Scaffold with Cross-Linked Collagen Coating	Porous Silicone and Nylon Knit Bi-layer Scaffold with Collagen Coating	Porous Silicone and Nylon Knit Bi-layer Scaffold with Cross-Linked Collagen Coating	Porous Silicone and Nylon Knit Bi-layer Scaffold with Collagen and Aloe Coating	Equivalent to predicate devices. The construction is equivalent to the primary predicate and the same as the Biobrane II predicate.
Indications for Use	FortiShield is indicated for: partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial	Temporary wound dressing for coverage of Superficial burns, Donor sites and Meshed autographs. AWBAT-S: is intended for clean Superficial burn wounds.	Covering donor sites, clean, debrided, or excised superficial and medium depth partial (2°) thickness wounds and as a protective covering over meshed autografts. Suggested Uses: To manage clean partial thickness wounds	PermeaDerm B is indicated for partial thickness burn wounds, donor sites and coverage of meshed autograft. PermeaDerm CW is indicated for partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-	Equivalent to predicate devices. The indicated applications are identical to PermeaDerm CW.

Characteristic	Subject Device	Predicate Devices			Comparison
	Organogenesis Inc. **FortiShield™**	**Aubrey, Inc.** **AWBAT-S, AWBAT-D, AWBAT-M** **(Primary Predicate)**	**Sterling Drug, Inc.** **Biobrane II** **(Other Predicate)**	**PermeaDerm, Inc.** **Permeaderm B and Permeaderm CW** **(Other Predicate)**	
	thickness burns, and skin tears) and draining wounds.	AWBAT-D: is intended for Donor sites after hemostasis has been established. AWBAT-M: is intended to be used as a protective covering for Meshed autografts.	For wet wound management to minimize fluid accumulation For use in situations where maximum passage of transudate is desired	Moh's, post-laser surgery, podiatric, wound dehiscence, trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.	
Device Dimensions	2" x 2" through 15" X 30"	Unknown	2.5" X 5" 5" X 5" 5" x 7.5" 5" X 15" 10" X 15"	Permeaderm B: 5"x10 10"x15" 15"x30" Permeaderm: CW 2.5" x 5" 5" x 5"	Equivalent to predicate devices. The range of sizes is within the maximum size offered for the predicate devices.
Sterility	Sterile, SAL 10^{-6}	Sterile	Sterile	Sterile, SAL 10^{-6}	Equivalent to predicate

Characteristic	Subject Device	Predicate Devices			Comparison
	Organogenesis Inc. **FortiShield™**	**Aubrey, Inc.** **AWBAT-S, AWBAT-D, AWBAT-M** **(Primary Predicate)**	**Sterling Drug, Inc.** **Biobrane II** **(Other Predicate)**	**PermeaDerm, Inc.** **Permeaderm B and Permeaderm CW** **(Other Predicate)**	
					devices. All devices are provided sterile.
Pyrogenicity	Non-pyrogenic	Unknown	Non-pyrogenic	Unknown	Equivalent to predicate devices. Both the subject and primary predicate devices are non-pyrogenic.
Bio-compatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Equivalent to predicate devices. All devices are deemed biocompatible based on ISO 10993 testing for their intended nature and

Characteristic	Subject Device	Predicate Devices			Comparison
	Organogenesis Inc. **FortiShield™**	**Aubrey, Inc.** **AWBAT-S, AWBAT-D, AWBAT-M** **(Primary Predicate)**	**Sterling Drug, Inc.** **Biobrane II** **(Other Predicate)**	**PermeaDerm, Inc.** **Permeaderm B and Permeaderm CW** **(Other Predicate)**	
					duration of contact.

Non-Clinical Mechanical Testing:

Mechanical testing conducted on the FortiShield device and the Biobrane II predicate device demonstrates that the following performance properties of the devices are equivalent: tensile elongation, fatigue, and water vapor transmission rate.

Biocompatibility Testing:

FortiShield was determined to be biocompatible based on ISO 10993-1 and "FDA General Guidance on Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process." Based on the intended use of FortiShield, the device is classified according to ISO 10993-1 as a surface device with prolonged (>24 hours to 30 days) contact with breached, compromised surfaces.

The following biological endpoints were included in the evaluation of the biological safety of FortiShield: irritation or intracutaneous reactivity, acute systemic toxicity, implantation, cytotoxicity, genotoxicity, hemolysis, material-mediated pyrogenicity, and chemical characterization (extractables and leachables) with toxicological risk assessment. The tests and chemical characterization were performed on the final, finished and sterile subject device and the device is considered to be biocompatible based on these results.

Conclusions:

The subject device and the predicate devices underwent evaluation that confirms equivalence in the intended use of each device, biocompatibility, performance, environment of use, and the principles of operation. Therefore, the subject device demonstrates substantial equivalence to the predicate devices.