July 1, 2022

Organogenesis Inc.
Kurdea Lyon
Program Manager, Regulatory Affairs
150 Dan Road
Canton, Massachusetts 02021

Re: K220317
Trade/Device Name: PuraPly® Micronized Wound Matrix (PuraPly® MZ)
Regulatory Class: Unclassified
Product Code: KGN
Dated: May 27, 2022
Received: June 1, 2022

Dear Kurdea Lyon:

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 Morabito, PhD
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)*
K220317

Device Name
PuraPly® Micronized Wound Matrix (PuraPly® MZ)

Indications for Use *(Describe)*
PuraPly® Micronized Wound Matrix (PuraPly® MZ) is intended for the management of wounds that include:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (e.g., donor sites/grafts, post-Mohs' surgery, post-laser surgery, Podiatric wound, and wound dehiscence).
- Trauma wounds (e.g., abrasions, lacerations, and skin tears)
- Partial thickness burns
- Draining wounds

The device is intended for single patient use only.

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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6. 510(k) Summary

Submitter Information per 21 CFR 807.92(a)(1)

SPONSOR:	Organogenesis Inc. 150 Dan Road Canton, Massachusetts, 02021

PRIMARY CONTACT:	Kurdea Lyon Manager, Regulatory Affairs Phone: (781) 401-1063 Email: klyon@organo.com
SECONDARY CONTACT:	John Ferros Vice President, Regulatory Affairs Phone: (781) 615-1833 Email: Jferros@organo.com

MANUFACTURER:	Organogenesis Inc. 150 Dan Road Canton, Massachusetts, 02021

DATE PREPARED per 21 CFR 807.92(a)(1):	May 27, 2022

Device Information per 21 CFR 807.92(a)(2)

TRADE NAME OF SUBJECT DEVICE:	PuraPly® Micronized Wound Matrix (PuraPly® MZ)

COMMON/USUAL NAME:	Dressing, Wound, Collagen

DEVICE CLASS:	Unclassified

UNCLASSIFIED REASON:	Pre-Amendment

PRODUCT CODE:	KGN

PREDICATE DEVICE:	Primary Predicate Device: PuraPly® Wound Matrix (K011026) FDA cleared under Trade Name: FortaDerm Reference Device: ACell MicroMatrix (K172399)

Device Description per 21 CFR 808.92(a)(4)

PuraPly® Micronized Wound Matrix (PuraPly® MZ) consists of micronized porcine collagen intended for the management of wounds. PuraPly® Micronized Wound Matrix is supplied as a dry powder of particle size of ≤ 1000µm. The device is sterile and packaged in a vial sealed in a single pouch.

Intended Use per 21 CFR 807.92(A)(5)

PuraPly ® Micronized Wound Matrix (PuraPly® MZ) is intended for the management of wounds.

Indications for Use per FORM FDA 3881

PuraPly® Micronized Wound Matrix (PuraPly® MZ) is intended for the management of wounds that include:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (e.g., donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric wounds, wound dehiscence,)
- Trauma wounds (e.g., abrasions, lacerations, and skin tears)
- Partial thickness burns
- Draining wounds

The device is intended for single patient use only. Do not reuse. Do not implant.

Indications for Use Characteristics Comparison

The subject and predicate devices have the same intended use and indication for use statement.

Technological Characteristics Comparison with the predicate device per 21 CFR 807.92(a)(6)

The technological characteristics comparison demonstrates that the subject device is substantially equivalent in intended use, design, materials, and operational principles to the previously cleared predicate devices.

Basis of Substantial Equivalence per 21 CFR 807.100(b)(2)(ii)(A)

The substantial equivalence of the subject device was determined as per the FDA guidance document, **"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"** and the analysis of the technological characteristics which include materials, design, and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A) demonstrates that the subject device is substantially equivalent to the predicate devices.

The subject device design and features are substantially equivalent to the predicate in terms of safety and effectiveness and do not raise any new questions of safety and effectiveness.

The performance testing, device comparison, and analysis demonstrate that the subject device is substantially equivalent to the predicate device.

The data generated in the performance test reports located in Section 19 compared the subject device to the predicate device and support a finding of substantial equivalence.

Comparison Table

Device Characteristics	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Discussion
Product Name	PuraPly® Micronized Wound Matrix PuraPly MZ	PuraPly® Wound Matrix	ACell™ MicroMatrix	N/A
Applicant	Organogenesis Inc.	Organogenesis Inc.	ACell Incorporated	
510(k) Number	K220317	K011026	K172399	
Classification Regulation	Unclassified	Unclassified	Unclassified	Substantially Equivalent
Product Code	KGN	KGN	KGN	Substantially Equivalent
Indications for Use	The intended use of PuraPly® Micronized is for the management of wounds including: • Partial and full thickness wounds • Pressure ulcers, Venous ulcers, Diabetic ulcers, Chronic vascular ulcers • Tunneled/undermined wounds • Surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric,	The intended use of PuraPly® is for the management of wounds including: • Partial and full thick wounds • Pressure ulcers, Venous ulcers, Diabetic ulcers, Chronic vascular ulcers • Tunneled/undermined wounds • Surgical wounds (donor sites/grafts, post-Moh's surgery, post	The intended use of Acell™ for the management of wounds including: • Partial and full thick 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)	Substantially Equivalent

	wound dehiscence,) • Trauma wounds (e.g., abrasions, lacerations, skin tears) • Partial thickness burns • Drainage wounds	laser surgery, podiatric, wound dehiscence) • Trauma wounds (abrasions, lacerations, skin tears) • Second-degree burns • Drainage wounds	• Trauma wounds (abrasions, lacerations, skin tears) • Second-degree burns • Drainage wounds	
Sterile	Gamma Irradiation	Gamma Irradiation	Electron Beam irradiation	The sterilization method for the subject device is substantially equivalent to the primary predicate. The difference in sterilization method between the primary and reference predicates raises no additional concerns of safety and efficacy as both products are provided sterile.
Materials	Porcine Collagen	Porcine Collagen	Porcine derived extracellular matrix known as urinary bladder matrix	The animal origin for the subject device is identical to the primary predicate. The difference in detailed origin between the subject device and reference

				device does not raise any question related to safety and efficacy as the material is similar and performance data demonstrated the products are substantially equivalent
Available sizes	100, 500, &1000 mg	2x4 cm to 6x9 cm	20 mg- 1000 mg	The available sizes for the subject device are in the range of the available sizes for the reference device. The sizes for the primary device are not applicable as it is not available in a powder formulation.
How supplied	Powder; for single use	Single or double layered sheet; for single use	Powder, for single use	The subject device and reference device are both supplied in a powder form and for single use.
Biocompatible	Yes	Yes	Yes	Substantially Equivalent

Performance Data Non-Clinical Test per 21 CFR 807.92(b)(1)

No performance standards applicable to this device have been adopted under section 514 of The FD&C Act. Organogenesis Inc. has applied the use of voluntary standards to PuraPly® MZ, including current ISO standards for biocompatibility tests. PuraPly® MZ conforms to the requirements of the voluntary standards used.

The following non-clinical battery of testing was performed:
The subject device was evaluated for the following parameters:

- Color
- Particle size
- Differential Scanning Calorimetry (DSC) temperature
- Absorption capacity
- Mixing ratio
- Endotoxin levels
- pH

Performance Data Conclusions per 21 CFR 807.92(b)(3)

The subject device utilizes the same intended use, material composition, and similar technological characteristics as the predicate devices. The non-clinical laboratory data supports the substantial equivalence of the subject device and the predicate device and demonstrates that any differences in technological characteristics do not raise any new questions of safety and effectiveness. Therefore, the subject device, PuraPly® MZ is substantially equivalent to the predicate devices identified throughout this submission. Below is a table that describes the biocompatibility study tests that were performed on the subject device, PuraPly® MZ.

Based on the ISO10993-1 guidance for industry, the battery of tests included the following:

- Cytotoxicity; ISO 10993-5 (2009)
- Sensitization; ISO 10993-10 (2010)
- Irritation; ISO 10993-10 (2010)
- Pyrogenicity; ISO 10993-11 (2017)

- Acute systemic Toxicity; ISO 10993-11 (2017)
- Sub-acute systemic toxicity/ Implantation; ISO 10993-6 (2016) and ISO 10993-11 (2017)
- Sub-chronic systemic toxicity; ISO 10993-6 (2016) and ISO 10993-11 (2017)
- Genotoxicity; ISO 10993-3 (2014) and ISO 10993-12 (2012)
- Large animal wound healing study; ISO 10993-6 (2016)

All tests were performed in compliance with ISO 10993-1, ISO 13485, and ISO 17025 standards, unless otherwise indicated specifically.