May 23, 2024

PrintBio, Inc.
Janet Vargo
Official Correspondnet
51-36 35th Street
Long Island City, New York 11101

Re: K232602
Trade/Device Name: 3DMatrix Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXF, OWT, OWZ, OXC
Dated: April 22, 2024
Received: April 22, 2024

Dear Janet Vargo:

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.05.23 12:29:01 -04'00'

Tek Lamichhane
Assistant Director
DHT4B: Division of Infection Control
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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)*
K232602

Device Name
3DMatrix Surgical Mesh ("3DMatrix")

Indications for Use *(Describe)*
3DMatrix is indicated for the reinforcement of soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery. Examples of applications where 3DMatrix may be used include:

- Suture line reinforcement including for hernia repair

- Muscle flap reinforcement

- General tissue reconstructions

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-K232602

1 SUBMITTER

PrintBio, Inc.
51-36 35th Street
Long Island City NY 11101
Regulatory Contact: Janet Vargo, PhD

Phone: 908-420-2707
email: jvargo@printbio.com

2 DATE PREPARED

May 23, 2024

3 DEVICE NAMES/CLASSIFICATION

Commercial Name: 3DMatrix
Common Name: Surgical Mesh
Regulation: 21CRF 878.3300
Regulatory Class: II
Product Codes: OXF, OWT, OWZ, OXC

4 PREDICATE DEVICES

Predicate Device Name: GORE® BIO-A® Tissue Reinforcement
510(k) Number: K163217

Reference Device: Polydioxanone Surgical Scaffold™
510(k) Number: K181094

Reference Device: Gore-Tex Soft Tissue Patch and Dualmesh
(**510(k) Number:** K963619

Reference Device: PDS Flexible Plate
510(k) Number: K092590

5 DEVICE DESCRIPTION

3DMatrix Surgical Mesh (3DMatrix) is a single-use, fully absorbable, colorless, non-woven, 3D-printed, macroporous, polymeric surgical mesh made entirely of uncolored and undyed polydioxanone (PDO). 3DMatrix is provided in two sizes, 60 mm x 55 mm and 60 mm x 145 mm that can be cut to the desired shape and size for each specific application at the time of use. 3DMatrix is terminally sterilized by Ethylene Oxide validated to an SAL of 10^{-6} and intended to be used by prescription only in a healthcare facility or hospital.

3DMatrix is a medical device used for surgical repair or reinforcement of soft tissue. Once implanted, 3DMatrix acts as a mechanical support to soft tissues and provides a scaffold for tissue ingrowth. It is designed to fully degrade over six to seven months. 3DMatrix provides temporary mechanical support and stabilization during the healing process.

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6 INDICATIONS FOR USE

3DMatrix is indicated for the reinforcement of soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery. Examples of applications where 3DMatrix may be used include:

- Suture line reinforcement including for hernia repair
- Muscle flap reinforcement
- General tissue reconstructions

7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The information provided in this premarket notification supports that the differences in mesh thickness, density, material (PDO vs. 67% polyglycolic acid [PGA] + 33% trimethylene carbonate [TMC]), sterilization method (ethylene oxide vs gamma radiation) between the subject and predicate mesh device raise no new issues of safety or effectiveness when used as intended. 3DMatrix does have similar density to the legally marketed reference device K963619; similar material, sterilization method, mesh thickness, and density as the legally marketed reference device K092590; and has similar material and sterilization method to legally marketed reference device K181094.

Table 1. Predicate and Reference Device Comparison Table – Technological Characteristics

	Subject Device – 3DMatrix	**Predicate- Gore® Bio-A® Tissue Reinforcement**	**Reference Device Polydioxanone Surgical Scaffold™**	**Reference Device - Gore® GORE-TEX® SOFT TISSUE PATCH**	**Reference Device - PDS Flexible Plate**	**Comparison**
510(k) number	K232602	K163217	K181094	K963619	K092590	NA
Classification	Class II, Surgical Mesh	Class II, Surgical Mesh	Class II, Surgical Mesh	Class II, Surgical Mesh	Class II; ear, nose and throat synthetic polymer material	Equivalent to predicate and reference devices K181094 and K963619
Indications for Use/Intended Use	Indicated for: the reinforcement of soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery. Examples of applications where 3DMatrix may be used include: -Suture line reinforcement including for hernia repair -Muscle flap reinforcement	Intended for: use in the reinforcement of soft tissue. This includes use in patients requiring soft tissue reinforcement in plastic and reconstructive surgery. Examples of applications where GORE® BIO-A® Tissue Reinforcement may be used include: -Hernia repair as suture line reinforcement	Intended for: use in reinforcement of soft tissue where weakness exists.	Intended for: Used for the reconstruction of hernias and for the temporary bridging of fascial defects and soft tissue deficiencies	Indicated for: -Nasal soft-tissue and cartilage reconstruction	Equivalent to predicate

	Subject Device – 3DMatrix	**Predicate- Gore® Bio-A® Tissue Reinforcement**	**Reference Device Polydioxanone Surgical Scaffold™**	**Reference Device - Gore® GORE-TEX® SOFT TISSUE PATCH**	**Reference Device - PDS Flexible Plate**	**Comparison**
	-General tissue reconstructions	-Muscle flap reinforcement -General tissue reconstructions				
Material	Polydioxanone (PDO) filament	67% polyglycolic acid (PGA): 33% trimethylene carbonate (TMC)	Polydioxanone (PDO) thread	ePTFE	Polydioxanone	Equivalent to reference devices K181094 and K092590
Use	Single Use	Single Use	Single Use	Single Use	Single Use	Equivalent to predicate and reference devices K181094, K963619 and K092590
Sterilization Mode & SAL	Ethylene Oxide, SAL 10^{-6}	Gamma, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}	Steam, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}	Equivalent to reference devices K181094 and K092590
Biodegradable	Yes	Yes	Yes	No	Yes	Equivalent to predicate and reference devices K181094 and K092590
Primary Mechanism of Degradation	Degradation via hydrolysis	Degradation via hydrolysis	Degradation via bulk hydrolysis	None	Degradation via hydrolysis	Equivalent to predicate and reference devices K181094 and K092590
Biocompatible	Yes	Yes	Yes	Yes	Yes	Equivalent to predicate and reference devices K181094, K963619 and K092590
Packaging	Double-layer Tyvek and polyethylene pouch, which is then sealed in a medical-grade foil pouch	Double-layer Tyvek and polyethylene pouch, which is then sealed in a medical-grade foil pouch	Not available	Double sterile barrier HDPE trays with TYVEK® packaging lids	Not available	Equivalent to predicate
Shelf Life	6 weeks	3 years	Not available	>3 years	Not available	Difference does not raise different questions of safety or effectiveness
Bioabsorption	6-7 months	6-7 months	9 months	None	6 months	Equivalent to predicate and reference

	Subject Device – 3DMatrix	**Predicate- Gore® Bio-A® Tissue Reinforcement**	**Reference Device Polydioxanone Surgical Scaffold™**	**Reference Device - Gore® GORE-TEX® SOFT TISSUE PATCH**	**Reference Device - PDS Flexible Plate**	**Comparison**
						device K092590
Storage	Room Temperature	Room Temperature	Room Temperature	Room Temperature	Below 25°C	Equivalent to predicate and reference devices K181094 and K963619
Shape	Rectangular	Rectangular, Square	Not available	Rectangular, Square	Rectangular	Equivalent to predicate and reference devices K963619 and K092590
Size (LxW)	60 x 55 mm 60 x 145 mm	70 x 100 mm 80 x 80 mm 90 x 150 mm 100 x 300 mm 200 x 200 mm 200 x 300 mm	Not available	50 x 100 mm 50 x 150 mm 100 x 150 mm 150 x 200 mm 200 x 300 mm	40 x 50 mm	Difference does not raise different questions of safety or effectiveness; within range of sizes across predicate and reference devices K963619 and K092590
Thickness	0.6 mm	1.57 ± 0.02 mm	Not available	1 or 2 mm	0.5 mm	Equivalent to reference device K092590
Density	392 g/m^2	Not available	Not available	400 g/m^2	625 g/m^2	Equivalent to reference device K963619

8 SUMMARY OF PERFORMANCE DATA

The data submitted in this application included benchtop and animal studies on biocompatibility, performance, packaging, sterilization, and shelf-life testing. Key performance characteristics of ball burst strength/force (ASTM D6797-15, Standard Test Method for Bursting Strength of Fabrics Constant-Rate-of-Extension (CRE) Ball Burst Test), suture pull-out strength (Internal Test Method), tear strength (ASTM D2261-13, Standard Test Method for Tearing Strength of Fabrics by the Tongue (Single Rip) Procedure (Constant-Rate-of-Extension Tensile Testing Machine), and tensile strength (ASTM D5035-11, Standard Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method) were substantially equivalent to the predicate device. The resulting data demonstrate that 3DMatrix functions as intended and performs comparably to the predicate device currently marketed for the same intended use.

All biocompatibility studies were conducted in compliance with Good Laboratory Practice (GLP) regulations (21 CFR Part 58) and in accordance with FDA Guidance for *Use of International*

Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued September 4, 2020).

9 CONCLUSIONS

Nonclinical testing results demonstrate that the device is as safe, as effective, and performs at least as well as the legally marketed predicate and reference devices identified in Section 4 of this summary.

The data support that the 3DMatrix device is substantially equivalent to the predicate device in terms of intended/indications for use, design, materials, function, biocompatibility, and sterilization.