May 21, 2025

PrintBio, Inc.
Janet Vargo
VP Regulatory Affairs
51-36 35th Street
Long Island City, New York 11101

Re: K243302
Trade/Device Name: 3DMatrix DynaFlex (DynaFlex)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXF, OWT, OWZ, OXC
Dated: December 20, 2024
Received: December 20, 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

Tek N. Lamichhane, 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

Enclosure

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.

510(k) Number *(if known)*
K243302

Device Name
3DMatrix DynaFlex (DynaFlex)

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

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510(k) SUMMARY

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 15, 2025

3 DEVICE NAMES/CLASSIFICATION

Commercial Name: 3DMatrix DynaFlex (DynaFlex)
Common Name: Surgical Mesh
Regulation: 21CRF 878.3300
Classification Name: Mesh, Surgical, Absorbable, Plastic and Reconstructive Surgery
Regulatory Class: II
Product Codes: OXF, OWT, OWZ, OXC

4 PREDICATE DEVICES

Predicate Device Name: 3DMatrix
510(k) Number: K232602

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

Reference Device: BARD LARGE PORE SOFT MESH AND SOFT MESH PRESHAPED
(**510(k) Number:** K052155

Reference Device: ULTRAPRO MESH
510(k) Number: K033337

5 DEVICE DESCRIPTION

3DMatrix DynaFlex ("DynaFlex") is a single-use, fully absorbable, colorless, non-woven, 3D-printed, macroporous, polymeric surgical mesh made entirely of uncolored and undyed polydioxanone (PDO). DynaFlex is provided in three sizes, 6 cm x 5.5 cm, 6 cm x 14.5 cm, and 5 cm x 17 cm, that can be cut to the desired shape and size for each specific application at the time of use. DynaFlex 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.

DynaFlex is a medical device used for surgical repair or reinforcement of soft tissue. Once

implanted, DynaFlex 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. DynaFlex provides temporary mechanical support and stabilization during the healing process. DynaFlex mesh is not isotropic so the mechanical properties of DynaFlex mesh are direction dependent.

6 INDICATIONS FOR USE

3DMatrix DynaFlex (DynaFlex) is indicated for the reinforcement of soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery. Examples of applications where DynaFlex 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

3DMatrix DynaFlex (DynaFlex) and the predicate 3DMatrix Surgical Mesh (3DMatrix) have the same indications and principle of operation. Both products have identical materials of composition, methods of manufacture, and packaging systems. Differences between DynaFlex and the predicate (density, pore size, and bi-directional mechanical properties) are characteristic of other FDA-cleared surgical meshes (reference devices K033337, K052155, and K163217) with very similar indications for use and do not raise new safety or effectiveness questions.

Mechanical and degradation testing completed on DynaFlex confirm equivalence to the predicate. Some of the biocompatibility testing, or sterilization validation were leveraged from the predicate device.

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

	Subject Device – DynaFlex	**Predicate – 3DMatrix**	**Reference Device - Gore® Bio-A® Tissue Reinforcement**	**Reference Device – Bard Large Pore Soft Mesh and Soft Mesh Preshaped**	**Reference Device – UltraPro**	**Comparison**
510(k) number	K243302	K232602	K163217	K052155	K033337	NA
Classification	Class II, Surgical Mesh	Class II, Surgical Mesh	Class II, Surgical Mesh	Class II, Surgical Mesh	Class II, Surgical Mesh	**Identical to predicate** and reference devices

	Subject Device – DynaFlex	**Predicate – 3DMatrix**	**Reference Device - Gore® Bio-A® Tissue Reinforcement**	**Reference Device – Bard Large Pore Soft Mesh and Soft Mesh Preshaped**	**Reference Device – UltraPro**	**Comparison**
510(k) number	K243302	K232602	K163217	K052155	K033337	NA
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 - General tissue reconstructions	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	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	Bard® Large Pore Soft Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. Bard Large Pore Soft Mesh Pre-Shaped is indicated for the repair of inguinal hernia defects.	ULTRAPRO Mesh may be used for the repair of hernias and other abdominal fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	**Identical to predicate** and equivalent to reference devices
Material	Polydioxanone (PDO)	Polydioxanon (PDO)	67% polyglycolic acid (PGA): 33% trimethylene carbonate (TMC)	Polypropylene	50% - absorbable poliglecaprone-25 50% - polypropylene	**Identical to predicate**
Use	Single Use	Single Use	Single Use	Single Use	Single Use	**Identical to predicate** and reference devices
Sterilization Mode & SAL	Ethylene Oxide SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}	Gamma SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}	**Identical to predicate** and equivalent to reference devices K052155 and K033337

	Subject Device – DynaFlex	**Predicate – 3DMatrix**	**Reference Device - Gore® Bio-A® Tissue Reinforcement**	**Reference Device – Bard Large Pore Soft Mesh and Soft Mesh Preshaped**	**Reference Device – UltraPro**	**Comparison**
510(k) number	K243302	K232602	K163217	K052155	K033337	NA
Biodegradable	Yes	Yes	Yes	No	Partial	**Identical to predicate** and equivalent to reference device K163217
Primary Mechanism of Degradation	Degradation via hydrolysis	Degradation via hydrolysis	Degradation via hydrolysis	None	Degradation of poliglecaprone-25 via hydrolysis	**Identical to predicate** and equivalent to reference device K163217
Biocompatible	Yes	Yes	Yes	Yes	Yes	**Identical or better than predicate** and equivalent to reference devices
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	Double-layer Tyvek and polyethylene pouch, which is then sealed in a medical-grade foil pouch	Tyvek-Film Pouch, in a cardboard storage box	Folded cardboard, which is sealed in a medical-grade foil pouch	**Identical to predicate** and equivalent to reference device K163217
Bioabsorption	6-7 months	6-7 months	6-7 months	None	84 days - poliglecaprone-25 component	**Identical to predicate** and equivalent to reference device K163217
Storage	Room Temperature	Room Temperature	Room Temperature	No special storage conditions	No special storage conditions	**Identical to predicate** and equivalent to reference device K163217
Shape	Rectangular	Rectangular	Rectangular, Square	Various Shapes	Various Shapes	Equivalent to predicate and reference devices
Pore Size (mm^2)	7.5 ± 0.2	1.21	Microporous	6.29	3.4	Equivalent to reference device K052155

	Subject Device – DynaFlex	**Predicate – 3DMatrix**	**Reference Device - Gore® Bio-A® Tissue Reinforcement**	**Reference Device – Bard Large Pore Soft Mesh and Soft Mesh Preshaped**	**Reference Device – UltraPro**	**Comparison**
510(k) number	K243302	K232602	K163217	K052155	K033337	NA
Density (g/m^2)	289	392	Not Available	43.7	34	Difference does not raise questions of safety or effectiveness
Bi-Directional Mechanics	Yes	No	No	Yes	Yes	Equivalent to reference devices K052155 and K033337

8 NON-CLINICAL TESTS SUMMARY & CONCLUSIONS

Nonclinical testing to demonstrate the product mechanical performance, mechanical and mass degradation, and bioabsorption were performed to determine substantial equivalence to the predicate. The nonclinical performance testing of DynaFlex demonstrated that the device is substantially equivalent to the predicate device in mechanical performance, mechanical and mass degradation kinetics , and in vivo bioabsorption.

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 data supporting substantial equivalence and biocompatibility of DynaFlex included all endpoints, including hemolysis, that are required for long-term implant devices with tissue and bone, in accordance with ISO 10993-1.

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) to address all endpoints for a long-term contact device.

9 CONCLUSIONS

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

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