June 12, 2025

Davol Inc.
Becca Defrancia
Senior Regulatory Affairs Associate
100 Crossings Blvd
Warwick, Rhode Island 02886

Re: K251557
Trade/Device Name: Bard® Mesh; Bard® Mesh Pre-Shaped
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 20, 2025
Received: May 21, 2025

Dear Becca Defrancia:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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)*
K251557

Device Name
Bard® Mesh; Bard® Mesh Pre-Shaped

Indications for Use *(Describe)*
Bard® Mesh is indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.
Bard® Mesh Pre-shaped is indicated for the repair of inguinal hernia defects.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K251557

Submitter:

Davol Inc., Subsidiary of C.R. Bard, Inc.
100 Crossings Blvd.
Warwick, RI 02886
United States

Contact: Becca DeFrancia
Title: Senior Regulatory Affairs Specialist
Email: becca.defrancia@bd.com

Date of Submission: May 21, 2025

Subject Device:

Device Trade Name:	Bard® Mesh; Bard® Mesh Pre-Shaped
Common Name:	Surgical mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Predicate Device:

Device Trade Name:	Bard® Mesh; Bard® Mesh Pre-Shaped
Common Name:	Surgical mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Device Description:

The Bard® Mesh is a nonabsorbable, sterile mesh designed for the reinforcement of soft tissue where weakness exists, i.e., repair of hernias and chest wall defects. The Bard® Mesh Pre-Shaped is a nonabsorbable, pre-trimmed sterile mesh designed for reinforcement of inguinal hernias. The Bard® Mesh is offered in several sizes of rectangular flat sheets and in several pre-shaped configurations, known as Bard® Mesh Pre-Shaped. Bard® Mesh product family products consist of the standard, rectangular or square sizes which can be trimmed as needed to provide surgeons with more freedom to customize the prosthesis prior to implantation. The Bard® Mesh portfolio currently ranges from 1” x 4” to 10” x 14” rectangle mesh. The Bard® Mesh is comprised of knitted polypropylene monofilaments in a square or rectangular flat sheet with selvage edges. The Bard Mesh Pre-Shaped is comprised of knitted polypropylene monofilaments in a pre-shaped configuration with a pre-cut into a shape commonly used by surgeons to protect the spermatic cord or similar structure as part of an inguinal hernia repair. All clinical, biological, and technical characteristics of the Bard® Mesh and Bard® Mesh Pre-Shaped are identical except that Bard® Mesh Pre-Shaped is only indicated for inguinal hernias due to the pre-cut/pre-shaped nature of the product.

Indications for Use:

Bard® Mesh is indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.

Bard® Mesh Pre-shaped is indicated for the repair of inguinal hernia defects.

Indications for Use Comparison to Predicate Device:

The subject device and predicate device have identical intended uses, which is for use in soft tissue reinforcement where weakness exists. The subject device indications reflect the definition of a surgical mesh given in 21 CFR 878.3300. The Bard® Mesh Pre-Shaped is only indicated for inguinal hernias. The differences between the subject device and predicate device indications do not constitute a new intended use, as both the subject and predicate device are indicated for the same tissue type (soft tissue) and disease entity (repair of hernias).

Technological Comparison to Predicate Device:

The subject device and predicate device have the same intended use and technological characteristics. The only differences between the subject and predicate device are modifications to the labeling and pre-shaped design for the subject device. These labeling and design modifications do not impact the safety or effectiveness of the subject device, nor do they impact the substantial equivalency between the subject and predicate devices. Based on the evidence, it can be concluded that the subject device, Bard® Mesh and Bard® Mesh Pre-Shaped, is substantially equivalent to the predicate device, Bard® Mesh preamendment device.

Device Characteristic	**Subject Device: Bard® Mesh, Bard® Mesh Pre-Shaped (K251557)**	**Predicate Device: Bard® Mesh, Bard® Mesh Pre-Shaped (Preamendment)**	**Comparison Assessment**
Device Classification	Class II Surgical Mesh 21 CFR 878.3300 Product Code: FTL	Class II Surgical Mesh 21 CFR 878.3300 Product Code: FTL	Identical
Intended Use	Soft tissue repair/reinforcement	Soft tissue repair/reinforcement	Identical
Indications for Use –Bard® Mesh	Bard® Mesh is indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.	Marlex® mesh constructed from knitted polypropylene is indicated for use in procedures for the repair of: 1) Recurrent inguinal hernias or direct inguinal hernias, particularly when fascial structures are weak. 2) Recurrent incisional hernias, or hernias so large that the fascial edges of the hernial ring cannot be approximated (generally one-fourth of the abdominal wall). 3) Chest wall defects where it is not possible to use autogenous tissue to prevent or correct lung herniation. 4) Recurrent femoral hernias.	Similar
Indications for Use – Bard® Mesh Pre-Shaped	Bard® Mesh Pre-shaped is indicated for the repair of inguinal hernia defects.	Bard Mesh Pre-shaped is indicated to reinforce soft tissue where weakness exists, i.e. repair of hernias and chest wall defects.	Similar
Principles of Operation	Insertion, Placement/Positioning, Fixation	Insertion, Placement/Positioning, Fixation	Identical
Materials	Polypropylene monofilament	Polypropylene monofilament	Identical

<table>
<tr><td>Design</td><td>Single layer knitted polypropylene monofilament mesh, rectangle and pre-shaped</td><td>Single layer knitted polypropylene monofilament mesh, rectangle</td><td>The pre-shaped design was introduced as a line extension in 1991. The rectangle design remains identical.</td></tr>
<tr><td>Sizes</td><td>Bard Mesh<table><tr><td>Code</td><td>Size</td></tr><tr><td>0112640</td><td>1” x 4”</td></tr><tr><td>0112650</td><td>2” x 4”</td></tr><tr><td>0112660</td><td>10” x 14”</td></tr><tr><td>0112670</td><td>2” x 12”</td></tr><tr><td>0112680</td><td>3” x 6”</td></tr><tr><td>0112720</td><td>6” x 6”</td></tr></table>Bard Mesh Pre-shaped<table><tr><td>Code</td><td>Size</td></tr><tr><td>0113700</td><td>2.4” x 5.4”</td></tr><tr><td>0112700</td><td>1.8” x 4”</td></tr><tr><td>0113710</td><td>2.4” x 5.4” (with Keyhole)</td></tr><tr><td>0112710</td><td>1.8” x 4” (with Keyhole)</td></tr></table></td><td>Bard Mesh (1975 Catalog)<table><tr><td>Code</td><td>Size</td></tr><tr><td>H41533-01264</td><td>1” x 4”</td></tr><tr><td>H41533-01266</td><td>10” x 14”</td></tr><tr><td>H41533-01267</td><td>2” x 12”</td></tr></table>Bard Mesh Pre-shaped (Line extension marketed in 1991)<table><tr><td>Code</td><td>Size</td></tr><tr><td>0113700</td><td>2.4” x 5.4”</td></tr><tr><td>0112700</td><td>1.8” x 4”</td></tr><tr><td>0113710</td><td>2.4” x 5.4” (with Keyhole)</td></tr><tr><td>0112710</td><td>1.8” x 4” (with Keyhole)</td></tr></table></td><td>Similar</td></tr>
<tr><td>Sterilization Method</td><td>Ethylene oxide</td><td>Ethylene oxide</td><td>Identical</td></tr>
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The purpose of this Special 510(k) notification is to obtain clearance of changes made to the Bard® Mesh family since it was placed on the market as a preamendment device in 1962. The changes proposed in this Special 510(k) that met the criteria for a premarket notification in accordance with FDA Guidance ‘Deciding When to Submit a 510(k) for a Change to an Existing Device’ issued on October 25, 2017 involve the indications for use and the Bard® Mesh Pre-Shaped line extension. There are no proposed modifications subject to this 510(k) that impact biocompatibility, sterilization, or any other aspect of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions:

Through the risk analysis conducted, it was determined that the labeling changes described in this Special 510(k) do not result in any new or increased risks. As there are no new or increased risks identified, no verification or validation activities are required for these labeling changes. Design verification testing was conducted to support the performance of the pre-shaped configuration.

Conclusion:

The subject device and predicate device have the same intended use and technological characteristics. The only differences between the subject and predicate device are modifications to the labeling and pre-shaped design for the subject device. These labeling and design modifications do not impact the safety or effectiveness of the subject device, nor do they impact the substantial equivalency between the subject and predicate devices. Therefore, the subject device, Bard® Mesh and Bard® Mesh Pre-Shaped, is substantially equivalent to the predicate device, Bard® Mesh preamendment device.