April 09, 2025

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

Re: K250098
Trade/Device Name: Bard Soft Mesh; Bard Soft Mesh Pre-Shaped
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: February 19, 2025
Received: February 19, 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.

Submission Number *(if known)*

K250098

Device Name

Bard Soft Mesh;
Bard Soft Mesh Pre-Shaped

Indications for Use *(Describe)*

Bard® Soft Mesh is indicated for the repair of ventral, incisional, and inguinal hernias.
Bard® Soft Mesh Pre-Shaped is indicated for the repair of inguinal hernias.

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
K250098

Submitter:

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

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

Date of Submission: Jan 14, 2025

Subject Device:

Device Trade Name:	Bard® Soft Mesh; Bard® Soft 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® Soft Mesh; Bard® Soft Mesh Pre-Shaped (K052155)
Common Name:	Surgical mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Device Description:

The purpose of this 510(k) is to notify FDA of the changes to the Bard® Soft Mesh and Bard® Soft Mesh Pre-Shaped labeling. There are no changes to the device itself. The device description is identical to the device description for the predicate device, Bard® Soft Mesh and Bard® Soft Mesh Pre-Shaped (K052155). The Bard® Soft Mesh is a nonabsorbable, sterile mesh designed for reinforcement of soft tissue deficiencies in adults with ventral, incisional, and inguinal hernias. The Bard® Soft Mesh Pre-Shaped is a nonabsorbable, sterile mesh designed for reinforcement of soft tissue deficiencies in adults with inguinal hernias. The knit construction allows the mesh to be stretched in both directions, in order to accommodate and reinforce tissue defects. The Bard® Soft Mesh is comprised of knitted polypropylene monofilaments in a rectangular flat sheet ranging from 2” x 4” to 12” x 12” with smooth radiused corners. The Bard® Soft Mesh Pre-Shaped is comprised of knitted polypropylene monofilaments in a pre-shaped configuration pre-cut into a shape commonly used by surgeons to protect the spermatic cord or similar structure as part of an inguinal hernia repair.

Indications for Use:

Bard® Soft Mesh is indicated for the repair of ventral, incisional, and inguinal hernias.

Bard® Soft Mesh Pre-Shaped is indicated for the repair of inguinal hernias.

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 specify use in the repair of ventral, incisional, and inguinal hernias while the predicate device indications are broad hernia repair indications. The Bard® Soft 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 is identical to the predicate device in terms of design, materials, manufacturing, packaging, sterilization, biocompatibility, and shelf-life.

Device Characteristic	Subject Device: Bard® Soft Mesh; Bard® Soft Mesh Pre-Shaped (K250098)	Predicate Device: Bard® Soft Mesh; Bard® Soft Mesh Pre-Shaped (K052155)	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	Same
Intended Use	Soft tissue repair/reinforcement	Soft tissue repair/reinforcement	Same
Indications for Use	Bard® Soft Mesh is indicated for the repair of ventral, incisional, and inguinal hernias. Bard® Soft Mesh Pre-Shaped is indicated for the repair of inguinal hernias.	Bard® Soft Mesh is indicated to reinforce soft tissue where weakness exists, e.g., repair of hernias and chest wall defects. Bard® Soft Mesh Pre-shaped is indicated for the repair of inguinal hernia defects.	Similar
Principles of Operation	• Insertion • Placement/Positioning	• Insertion • Placement/Positioning	Same
Materials	Polypropylene monofilament	Polypropylene monofilament	Same
Design	Single layer knitted polypropylene monofilaments	Single layer knitted polypropylene monofilaments	Same
Sizes	**2”X4” Rectangle Bard Soft Mesh 3”X6” Rectangle Bard Soft Mesh 4”X6” Rectangle Bard Soft Mesh 6”X6” Square Bard Soft Mesh 12”X12” Square Bard Soft Mesh 1.8”X4.0” Bard Soft Mesh Pre-shaped 1.8”X4.0” Bard Soft Mesh Pre-shaped with Keyhole 2.4”X5.4” Large Bard Soft Mesh Pre-shaped 2.4”X5.4” Large Bard Soft Mesh Pre-shaped with Keyhole**	**2”X4” Rectangle Bard Soft Mesh 3”X6” Rectangle Bard Soft Mesh 4”X6” Rectangle Bard Soft Mesh 6”X6” Square Bard Soft Mesh 1.8”X4.0” Bard Soft Mesh Pre-shaped 1.8”X4.0” Bard Soft Mesh Pre-shaped with Keyhole 2.4”X5.4” Large Bard Soft Mesh Pre-shaped 2.4”X5.4” Large Bard Soft Mesh Pre-shaped with Keyhole**	Similar
Sterilization Method	Ethylene oxide	Ethylene oxide	Same

The purpose of this 510(k) is to notify FDA of labeling updates to the Bard® Soft Mesh and Bard® Soft Mesh Pre-Shaped that are being made to comply with the requirements of the European medical device regulation, Regulation (EU) 2017/745, as well as documentation of historical product changes made via documentation to file including Bard® Soft Mesh size extension (i.e. addition of 12" x 12"). These modifications do not impact the substantial equivalence between the subject and predicate device and align the labeling of Bard® Soft Mesh and Bard® Soft Mesh Pre-Shaped with the labeling of other devices across the Davol Inc. hernia mesh portfolio. The predicate device and the subject device are substantially equivalent in all aspects.

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

Through the risk analysis conducted, it was determined that the labeling changes described in this 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. Non-clinical testing including mesh thickness, mesh knit construction, mesh pore size, mesh density, tensile strength, device stiffness, ball burst (strength), tear resistance, device stiffness, and suture pull out were considered in accordance with *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* issued on March 2, 1999. The non-clinical testing supported those historical changes taken under documentation to file, including dimensional line extension, do not impact the safety or effectiveness of the subject device nor do they impact the substantial equivalence between the subject and predicate devices.

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 for the subject device. These labeling 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. Additional changes taken under documentation to file since the clearance of K052155 were also found to have no impact to the substantial equivalence of the subject device. Therefore, the subject device, Bard® Soft Mesh and Bard® Soft Mesh Pre-Shaped, is substantially equivalent to the predicate device, Bard® Soft Mesh and Bard® Soft Mesh Pre-Shaped (K052155).