



June 30, 2024

Davol Inc., Subsidiary of C.R. Bard, Inc.
Richard Spaziano
Staff Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K233402
Trade/Device Name: Bard 3DMax Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL

Dear Richard Spaziano:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on November 1, 2023. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Tek N. Lamichhane, Office of Surgical and Infection Control Devices, 301-796-8983, Tek.Lamichhane@fda.hhs.gov

Sincerely,

Tek N. Lamichhane -S
Digitally signed by
Tek N. Lamichhane -S
Date: 2024.06.30
21:43:08 -04'00'

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



June 30, 2024

Davol Inc., Subsidiary of C.R. Bard, Inc.
Richard Spaziano
Staff Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K233402

Trade/Device Name: Bard 3DMax Mesh

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical Mesh

Regulatory Class: Class II

Product Code: FTL

Dated: October 4, 2023

Received: October 4, 2023

Dear Richard Spaziano:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on November 1, 2023.

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 and Part 809); 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: 2024.06.30
21:46:47 -04'00'

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

Indications for Use

510(k) Number (if known)
K233402

Device Name
Bard 3DMax Mesh

Indications for Use (Describe)

Bard® 3DMax™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in 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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Office of Chief Information Officer
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PRASStaff@fda.hhs.gov

"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
K233402**

Submitter:

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

Phone: (401) 825-8566

Contact: Richard Spaziano
Title: Staff Regulatory Affairs Specialist
Email: richard.spaziano@bd.com

Date of Submission: October 31, 2023

Subject Device:

Device Trade Name:	Bard® 3DMax™ Mesh
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® 3DMax™ Mesh (K081010), cleared on October 7, 2008
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 Special 510(k) is to notify FDA of the changes to the Bard® 3DMax™ Mesh labeling. There are no changes to the device itself. The device description is identical to the device description for the predicate device, Bard® 3DMax™ Mesh (K081010).

The Bard® 3DMax™ Mesh is anatomically designed to fit the inguinal anatomy. The device is curve shaped and preformed with sealed edges that allow for easier positioning of the device than a traditional flat sheet of mesh in a laparoscopic inguinal hernia repair. The device is constructed of knitted polypropylene monofilaments 7.5 millimeters in diameter. The knit construction allows the mesh to be stretched in both directions in order to accommodate and reinforce tissue defects. The device contains an orientation marker in an M shape with an arrow to facilitate mesh positioning and placement.

Indications for Use:

Bard® 3DMax™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in 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 inguinal hernias while the predicate device indications are broad hernia repair indications. 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. The purpose of this Special 510(k) is to notify FDA of labeling updates to the Bard® 3DMax™ Mesh that are being made to comply with the requirements of the European medical device regulation, Regulation (EU) 2017/745, as well as to align the labeling with other hernia mesh devices across the Davol Inc. portfolio. These labeling modifications do not impact the substantial equivalence between the subject and predicate device.

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

No non-clinical or clinical testing was provided in support of this Special 510(k).

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. Therefore, the subject device, Bard® 3DMax™ Mesh, is substantially equivalent to the predicate device, Bard® 3DMax™ Mesh (K081010).