February 19, 2025

Davol, Inc., a subsidiary of C.R. Bard, Inc.
Shannon Green
Manager, Regulatory Affairs
100 Crossings Blvd
Warwick, Rhode Island 02886

Re: K243241
Trade/Device Name: Phasix™ ST Umbilical Hernia Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWT, OOD, FTL
Dated: October 8, 2024
Received: October 10, 2024

Dear Shannon Green:

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

Digitally signed by Tek N. Lamichhane -S
Date: 2025.02.19 22:27:19 -05'00'

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)*

K243241

Device Name

Phasix ST Umbilical Hernia Patch

Indications for Use *(Describe)*

Phasix™ ST Umbilical Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving the repair of umbilical 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.

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

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**Phasix™ ST Umbilical Hernia Patch**

**(K243241)**

**510(k) Summary**
**21 CFR 807.92**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

**Submitter Information:**

Davol, Inc.
C.R. Bard, Inc.
100 Crossings Blvd
Warwick, RI 02886

Phone: (401) 825-8774
Fax: (401) 825-8765

Contact Person: Shannon Green
Title: Manager, Regulatory Affairs
Email: shannon.green2@bd.com

Date Prepared: February 19, 2025

**Subject Device Name:**

| | |
|---|---|
| Name of Device: | Phasix™ ST Umbilical Hernia Patch |
| Common or Usual Name: | Surgical Mesh |
| Classification Name: | Mesh, Surgical, Absorbable, Abdominal Hernia |
| Regulatory Class: | Class II |
| Regulation Number: | 21 CFR 878.3300 |
| Product Codes: | OWT, OOD, FTL |

**Primary Predicate Device:**

| | |
|---|---|
| Name of Device: | Ventralex™ ST Hernia Patch (K101928), cleared on March 23, 2011 |
| Common or Usual Name: | Surgical Mesh |
| Classification Name: | Mesh, Surgical, Polymeric |
| Regulatory Class: | Class II |
| Regulation Number: | 21 CFR 878.3300 |
| Product Code: | FTL |

**Secondary Predicate Device:**

| | |
|---|---|
| Name of Device: | Phasix™ ST Mesh with Open Positioning System (K190185), cleared on June 12, 2019 |
| Common or Usual Name: | Surgical Mesh |
| Classification Name: | Mesh, Surgical, Absorbable, Abdominal Hernia |
| Regulatory Class: | Class II |
| Regulation Number: | 21 CFR 878.3300 |
| Product Codes: | OWT, OOD, FTL |

**Reference Devices:**

Phasix™ Mesh (K142818), cleared March 31, 2015
Phasix™ ST Mesh (K143380), cleared June 5, 2015

**Device Description:**

Phasix™ ST Umbilical Hernia Patch is a sterile, single-use device for prescription use only. It is a self-expanding, fully resorbable mesh with a resorbable hydrogel coating and a positioning pocket and strap. Phasix™ ST Umbilical Hernia Patch is comprised of 2 layers of poly-4-hydroxybutyrate (P4HB), with the posterior side being co-knitted with polyglycolic acid (PGA) fibers, identical to the mesh component of the secondary predicate device (Phasix™ ST Mesh with Open Positioning System). P4HB degrades through hydrolysis and a hydrolytic enzymatic digestive process and is essentially completely resorbed in 12-18 months. Phasix™ ST Umbilical Mesh is coated on the PGA surface with a resorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC), and polyethylene glycol (PEG) based hydrogel. The hydrogel is identical to both the primary predicate device (Ventralex™ ST Hernia Patch (K101928) and the secondary predicate device (Phasix™ ST Mesh with Open Positioning System, K190185). The fascial side of the mesh allows for a prompt fibroblastic response through the interstices of the mesh, allowing for complete tissue ingrowth. The visceral side of the mesh is the resorbable hydrogel coating, which separates the mesh from underlying tissues and organ surfaces to help minimize tissue attachment to the mesh. Shortly after hydration in saline, the coating becomes a hydrated gel that is resorbed from the site in less than 30 days. Phasix™ ST Umbilical Hernia Patch contains SorbaFlex™ Memory Technology, which provides memory and stability to the mesh, facilitating ease of initial insertion, proper placement and fixation of the device. The SorbaFlex™ Memory Technology is comprised of an extruded polydioxanone (PDO) resorbable monofilament contained within a knitted P4HB containment sleeve. PDO is resorbed within 24-32 weeks. The PDO ring and hybrid positioning straps (comprised of P4HB and polypropylene materials that are connected by overlapping the materials and sewing them together with clear PP monofilament, with a delineation marker dyed blue with

[phthalocyaninato(2-)] copper), are based on the design of the primary predicate Ventralex™ ST Hernia Patch (K101928). The subject device has the identical intended use as the primary and predicate devices; soft tissue repair/reinforcement.

**Indications for Use of Device:**

The Phasix™ ST Umbilical Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving the repair of umbilical hernias.

**Technological Comparison to Predicate Devices:**

The subject device, Phasix™ ST Umbilical Hernia Patch, has the following similarities to the predicate devices:

- The intended use of the subject device, i.e. for the repair/reinforcement of soft tissue, is identical to Ventralex™ ST Hernia Patch (K10128) and Phasix™ ST Mesh with Open Positioning System (K190185).
- The indications for use, i.e. umbilical hernia repair, is similar to Ventralex™ ST Hernia Patch (K101928) and Phasix™ ST Mesh with Open Positioning System (K190185).
- The mesh design is similar to Ventralex™ ST Hernia Patch (K101928).
- The mesh sizes are identical to Ventralex™ ST Hernia Patch (K101928).
- The principle of operation for hernia repair is similar to Ventralex™ ST Hernia Patch (K101928).
- The poly-4-hydroxybutyrate (P4HB) co-knitted with polyglycolic acid (PGA) fibers which are coated with chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC), and polyethylene glycol (PEG) materials are identical to the materials of Phasix™ ST Mesh with Open Positioning System (K190185).
- The polydioxanone (PDO) ring, as well as the polypropylene and dyed polypropylene components of the positioning straps are identical to the materials of Ventralex™ ST Hernia Patch.
- The sterilization method (ethylene oxide) is identical to Ventralex™ ST Hernia Patch (K101928) and Phasix™ ST Mesh with Open Positioning System (K190185).

The subject device, Phasix™ ST Umbilical Hernia Patch, incorporates the following changes as compared to the predicate devices:

- The positioning strap of the subject device is a hybrid of both resorbable poly-4-hydroxybutyrate (P4HB) and non-resorbable polypropylene as compared to the polypropylene only strap of the primary predicate Ventralex™ ST Hernia Patch and includes a delineation marker to identity where to cut excess strap material to ensure no polypropylene is left behind. The marker is dyed blue with [phthalocyaninato (2-)] copper.
- There is no pre-attached, removable positioning system with the subject device as compared to the secondary predicate Phasix™ ST Mesh with Open Positioning System (K190185).

Phasix™ ST Umbilical Hernia Patch has the identical intended use as both the primary and secondary predicate devices. The subject device has similar indications for use as both the primary and secondary predicate device. The subject device is manufactured from material identical to the mesh component of the secondary predicate device and incorporates the identical PDO ring and polypropylene component of the positioning strap as the primary predicate device. Phasix™ ST Umbilical Patch has identical packaging materials as the primary predicate device. The subject device has the identical sterilization method (ethylene oxide) as compared to the predicate devices and similar principle of operation and manufacturing processes as compared to the predicate devices. Any differences in the technological characteristics were thoroughly tested and the results demonstrate that there are no new questions of safety and effectiveness.

**Performance Data:**

The following performance data is provided in support of substantial equivalence determination.

1. **Performance Standards:**
   No performance standards have been established for this device under Section 514 of the Federal Food, Drug and Cosmetic Act.

2. **Biocompatibility Testing:**
   The biocompatibility evaluation for Phasix™ ST Umbilical Patch was conducted in accordance with the Guidance for Industry and Food and Drug Administration Staff Use

of International Standard ISO 10993-1, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" September 8, 2023, and International Standard ISO 10993-1 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*," as recognized by the FDA.

The subject device mesh materials are identical to the mesh materials utilized in the successful clearance of the primary predicate Ventralex™ ST Hernia Patch (K101928) and the secondary predicate Phasix™ ST Mesh with Open Positioning System (K190185), and therefore considered safe and biocompatible. Utilizing the Biocompatibility Evaluation Flow Chart, Attachment D of the Guidance for Industry and Food and Drug Administration Staff Use of International Standard ISO 10993-1, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" (September 8, 2023), it has been concluded that all biocompatibility requirements are met. Thus, the tests specific to the individual materials of Phasix™ ST Umbilical Hernia Patch were not repeated. However, in order to address any risks associated with the interaction of materials that have not previously been combined in a single device, i.e. poly-4-hdyroxybutyrate (P4HB) and polydioxanone (PDO) and the interaction of the subject device with the packaging materials, chemical characterization and biological characterization testing were completed. As all materials of the subject device are utilized in the predicate devices, which are owned by Davol, Inc. and well known and have a greater than ten (10) year history of clinical use in the same anatomical space, comparative testing was not conducted. Refer to **Table 1**.

**Table 1: Biocompatibility Testing of Phasix™ ST Umbilical Hernia Patch**

| **Test Method** | **Results** |
|---|---|
| Material Chemical Characterization<br>Exhaustive Extraction at 50ºC for 72 hrs | PASS |
| Water | Gravimetric Analysis<br>GCMS<br>LCMS-UV-CAD<br>HS-GCMS<br>ICPMS<br>GPC |
| Ethanol | Gravimetric Analysis<br>GCMS<br>LCMS-UV-CADS |
| Hexane | |

| | |
|---|---|
| | GPC |
| **Cytotoxicity – Packaging Materials** | |
| MEM Cell Cytotoxicity – Tyvek Envelope | PASS |
| MEM Cell Cytotoxicity – Foil Pouch | PASS |
| **Cytotoxicity - Device** | |
| MEM Cell Cytotoxicity | PASS |
| Sensitization (Kligman Maximization) | PASS |
| Irritation / Intracutaneous Reactivity (Intracutaneous Injection) | PASS |
| Acute Systemic Toxicity | PASS |
| Material Mediated Pyrogenicty | PASS |
| Limulus Amebocyte Lysate (LAL) | PASS |
| Subacute Toxicity Study in Rats (28 days) | PASS |
| Subchronic Toxicity Study in Rats (13 weeks) | PASS |
| Chronic Toxicity (26 weeks) | PASS |
| Genotoxicity<br>• AMES Assay<br>• Mouse Lymphoma Assay | <br>• PASS<br>• PASS |
| Implantation (Intramuscular Implantation Test)<br>• 4 weeks<br>• 8 weeks<br>• 13 weeks<br>• 26 weeks | <br>• PASS<br>• PASS<br>• PASS<br>• PASS |
| Toxicology (Toxicological Risk Assessment) | PASS |

The biologic and chemical characterization test results demonstrate that the subject device is biocompatible and there are no interactions between the subject device new combination of materials, or the subject device and the packaging materials to affect the previously established safety and effectiveness. Therefore, the subject device is safe and is biocompatible for its intended use.

**3. Product Testing:**

The performance test results demonstrate that the subject device successfully met the established acceptance criteria and is substantially equivalent to Phasix™ ST Mesh with Open Positioning System (K190185) and Ventralex™ ST Hernia Patch (K101928). Completed performance testing on the subject device is listed in **Table 2**.

**Table 2: Performance Testing**

| Performance Test | |
|---|---|
| Substantial Equivalency Testing – Physical and Functional Characteristics | Physical Characteristics<br>– Mesh Weave Characteristics<br>– Pore Size<br>– Determination of Device and Mesh Thickness<br>– Weight per Unit Area (Linear Density)<br>– Device Stiffness<br>– Dimensional Measurements<br>Functional Characteristics<br>– Ball Burst Strength<br>– Suture Retention Strength (Machine and Cross directions)<br>– Tear Strength (Cross and Machine directions)<br>– PGA Pull-Out Strength<br>– Three-Tack Pluck Force<br>– Gel Disruption Analysis |
| Functional Testing of the Subject Device | – 25 Degree Recoil<br>– Containment Sleeve Puncture<br>– Strap Attachment Strength<br>– Pocket Integrity |
| Resorption Profile of the Ring and Containment Sleeve | – *In-vitro* degradation of PDO with Phasix and Phasix ST<br>– *In-vitro* degradation of PDO with Phasix ST (PGA pull-out) |
| Design Validation Usability Testing | – IFU<br>– Packaging/Labeling<br>– Insertion<br>– Positioning/Placement<br>– Fixation |
| Human Factors / Simulated Testing | – IFU<br>– Packaging/Labeling<br>– Device Preparation<br>– Insertion<br>– Positioning and Placement<br>– Fixation |

4. **Animal Studies:**

Animal studies were not conducted on the subject device. Based on identical materials and substantially equivalent properties measured through bench testing, *in-vivo* safety and performance of the subject device was evaluated through the animal and histological data presented in the reference devices: Phasix™ Mesh (K142818) and Phasix™ ST Mesh (K143380), which were utilized to support the clearance of the secondary predicate device, Phasix™ ST Mesh with Open Positioning System (K190185).

In addition, Phasix™ ST Mesh with Open Positioning System (K190185) was studied in a comprehensive 4 week GLP study in a porcine model. The subject device, Phasix™ ST Umbilical, is comprised of the same combination of poly-4-hydroxybutyrate (P4HB), polyglycolic acid (PGA) and chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC), and polyethylene glycol (PEG). The polydioxanone (PDO) ring in the subject device is identical to the primary predicate Ventralex™ ST Hernia Patch (K101928) and the material was evaluated via a rat model over 1, 2, 4, 8,12,16, 24 and 32 weeks. Based on the studies conducted for the reference devices as well as for both predicate devices, additional testing was not required for the subject device.

**Conclusion:**

Phasix™ ST Umbilical Hernia Patch has the identical intended use, materials of construction, packaging materials and sterilization method as the primary and secondary predicate devices. Furthermore, the subject device has similar indications for use, technological characteristics, principle of operation, and manufacturing processes as the primary and secondary predicate devices. Any differences in the technological characteristics between the subject device and the predicate devices were thoroughly assessed and evaluated. All test results support that the subject device's safety, effectiveness and performance are similar to the predicate devices. Therefore, Phasix™ ST Umbilical Hernia Patch is substantially equivalent to Ventralex™ ST Hernia Patch (K101928) and Phasix™ ST Mesh with Open Positioning System (K190185).