



September 28, 2026

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

Re: K261543

Trade/Device Name: Phasix ST Parastomal Hernia Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWT, OOD, FTL
Dated: May 8, 2026
Received: May 8, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

510(k) Number (if known)

K261543

Device Name

Phasix™ ST Parastomal Hernia Mesh

Indications for Use (Describe)

Phasix™ ST Parastomal Hernia Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures for the repair of parastomal 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.

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**510(k) Summary
K261543**

Submitter Information:

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

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

Date Prepared: September 25, 2026

Subject Device Name:

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

Predicate Device:

Name of Device:	BioDesign® Parastomal Hernia Repair Graft (K162934)
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical
Regulatory Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	FTM, FTL, OXK

Reference Device:

Name of Device:	Phasix™ ST Mesh (K143380)
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical
Regulatory Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	OWT, FTL, OOD

Device Description:

Phasix™ ST Parastomal Hernia Mesh is a sterile, single-use device for prescription use only. It is comprised of bioabsorbable poly-4-hydroxybutyrate (P4HB), co-knitted with polyglycolic acid (PGA) fibers, identical to the reference device (Phasix™ ST Mesh). P4HB degrades through hydrolysis and a hydrolytic enzymatic digestive process and is essentially completely absorbed in 12-18 months. Phasix™ ST Parastomal Hernia Mesh is coated on the PGA surface with an absorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC), and polyethylene glycol (PEG) based hydrogel. The hydrogel is identical to the reference device (Phasix™ ST Mesh). 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 absorbable hydrogel coating, which separates the mesh from underlying tissues and organ surfaces to help minimize tissue attachment to the mesh. Once hydrated, the hydrogel coating is essentially absorbed from the implant site in less than 30 days. The subject device has the identical intended use as the predicate and reference devices: soft tissue repair/reinforcement. The subject device involves a design change to the reference device, Phasix™ ST Mesh (K143380), with the modification consisting of the addition of a thermoformed, anatomically shaped channel. This channel is designed to accommodate the lateralized bowel in a Sugarbaker technique for parastomal hernia repair. The channel feature has the same absorbable hydrogel coating as the visceral side of the mesh and has a two-colored PGA marker around the perimeter to aid in determining mesh sidedness and placement over the lateralized bowel. This design modification facilitates the usability in parastomal hernia repair over flat mesh, specifically those repairs using a Sugarbaker technique.

Indications for Use of Device:

Phasix™ ST Parastomal Hernia Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving the repair of parastomal hernias.

Technological Comparison to Predicate and Reference Devices:

Device Characteristic	Phasix™ ST Parastomal Hernia Mesh (Subject Device)	BioDesign (K162934) (Predicate Device)	Phasix™ ST Mesh (K143880) (Reference Device)	Comparison
Intended Use	Soft tissue repair/reinforcement	Soft tissue repair/reinforcement	Soft tissue repair/reinforcement	Same
Indications for Use	Phasix™ ST Parastomal Hernia Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures for the repair of parastomal hernias.	Biodesign® Parastomal Hernia Repair Graft is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal wall defects and hernias, including but not limited to parastomal hernias.	Phasix™ ST Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias, including hiatal hernias.	The subject device and the predicate and reference devices are all indicated for repair/reinforcement of soft tissue, such as hernias. The subject device, like the predicate device, includes additional information on examples of soft tissue to be repaired.
Principles of Operation	Insertion, Placement, Fixation	Insertion, Placement, Fixation	Insertion, Placement, Fixation	Same
Materials	Posterior (Visceral) Mesh Side: P4HB monofilament; PGA (undyed [beige] and violet dyed) multifilament; HA/CMC PEG based hydrogel coating on PGA surface Anterior (Fascial) Mesh Side: P4HB monofilament Channel Coating: HA/CMC PEG based hydrogel Channel Marker: PGA (undyed [beige] and violet dyed) multifilament	Graft: Porcine small intestinal submucosa (extracellular matrix – primarily collagen types I, III, IV and VI) and PGA Channel Coating: N/A Channel Marker: N/A	Posterior (Visceral) Mesh Side: P4HB monofilament; PGA (undyed [beige] and violet dyed) multifilament; HA/CMC PEG based hydrogel coating on PGA surface Anterior (Fascial) Mesh Side: P4HB monofilament Channel Coating: N/A Channel Marker: N/A	Mesh materials are identical in composition to the reference device.

Device Characteristic	Phasix™ ST Parastomal Hernia Mesh (Subject Device)	BioDesign (K162934) (Predicate Device)	Phasix™ ST Mesh (K143880) (Reference Device)	Comparison
Absorption Profile	P4HB: essentially complete in 12-18 months PGA: essentially complete in 5 months Hydrogel: essentially complete in <30 days	N/A; device remodels and does not have a stated absorption profile	P4HB: essentially complete in 12-18 months PGA: essentially complete in 5 months Hydrogel: essentially complete in <30 days	Material absorption profiles are identical to the reference device.
Design	P4HB co-kitted with PGA and coated with an absorbable HA/CMC/PEG hydrogel forms the posterior side and P4HB mesh forms the anterior side. Thermoformed channel with hydrogel coating and PGA marker.	Multiple layers of porcine Small Intestinal Submucosa (SIS), a bioabsorbable, extracellular collagen matrix (ECM) that is non-crosslinked and decellularized. The device is held together with biodegradable PGA suture and is perforated.	P4HB co-kitted with PGA and coated with an absorbable HA/CMC/PEG hydrogel forms the posterior side and P4HB mesh forms the anterior side.	Similar to the reference device.
Sizes		Range of sizes from 5cm x 8cm to 30cm x 30cm	Range of circle sizes from 8cm to 15cm and rectangle/square sizes from 13cm x 25cm to 30cm x 35cm	Similar; subject device sizes are within the size range of the predicate and reference devices.
	Mesh Dimensions			
	18cm x 18cm			
	18cm x 18cm			
Packaging materials and configuration	The device is held within a polypropylene clamshell tray which is then sealed inside a foil pouch. The foil pouch is placed into an SBS carton.	The device is packaged dry within a small, sealed Tyvek/poly pouch, which is placed inside a larger, sealed Tyvek/poly pouch. The larger pouch is placed in a carton.	The device is placed in a Tyvek envelope which is placed into a foil pouch. The sealed foil pouch is placed into an SBS folder carton.	Similar to the predicate and reference devices.
Sterilization	Ethylene Oxide SAL 10 ⁻⁶	Ethylene Oxide	Ethylene Oxide SAL 10 ⁻⁶	Same

The subject device, Phasix™ ST Parastomal Hernia Mesh, incorporates the following changes as compared to the reference device:

- There is a thermoformed, anatomically shaped channel, designed to accommodate the lateralized bowel in a Sugarbaker technique for parastomal hernia repair. The channel feature has the same absorbable hydrogel coating as the visceral side of the mesh and has a two-colored PGA marker around the perimeter to aid in determining mesh sidedness and placement of the lateralized

bowel. The intent of this design change is to aid in mesh usability in parastomal hernia repairs.

Phasix™ ST Parastomal Hernia Mesh has the identical intended use as both the predicate and reference devices. The subject device has identical indications for use as the predicate device. The subject device is manufactured from materials identical to the reference device. Phasix™ ST Parastomal Hernia Mesh has similar packaging materials as the reference device. The subject device has identical sterilization method (ethylene oxide) as compared to both the predicate and reference devices and similar principles of operation and manufacturing processes as compared to the reference device. 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:

All of the device materials are identical to the materials used in the currently marketed Phasix™ ST Mesh (P4HB, PGA, ST hydrogel) and Phasix™ ST Parastomal Hernia Mesh contains less hydrogel and PGA than the largest Phasix ST Mesh (K143380). The thermoforming process used to create the channel is already performed on GalaFLEX 3D Scaffold (K161092) and occurs at a lower processing temperature than other existing manufacturing processes for P4HB and PGA. Thermoforming does not impact biocompatibility. Phasix™ ST Parastomal Hernia Mesh has undergone testing to hydrogel absorption (essentially complete in < 30 days), including cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, subacute toxicity, implantation, and genotoxicity testing, in addition to chemical characterization.

Chemical characterization will support the subchronic toxicity, chronic toxicity and carcinogenicity endpoints for Phasix™ ST Parastomal Hernia Mesh.

As the subject device mesh materials are identical to the materials utilized in the successful clearance of the reference device, Phasix™ ST Mesh (K143380), long-term implantation studies conducted on Phasix™ ST Mesh are representative of the subject device. Refer to [Table 1](#).

The biocompatibility evaluation for Phasix™ ST Parastomal Hernia Mesh 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.

Table 1: Biocompatibility Testing of Phasix™ ST Parastomal Mesh

Test Method	Results
Subject Device Testing	
MEM Cell Cytotoxicity	PASS
Sensitization (Kligman Maximization)	PASS
Irritation (Skin Irritation in Rabbits)	PASS
Acute Systemic Toxicity	PASS
Material Mediated Pyrogenicity	PASS
Subacute Systemic Toxicity Study in Rats (28 days)	PASS
Implantation (Intramuscular Implantation Test) – 4 weeks	PASS
Genotoxicity • AMES Assay • Mouse Lymphoma Assay	• PASS • PASS
Chemical Extractables Analysis - PLUS	PASS

Table 2: Biocompatibility Testing of Reference Device, Phasix™ ST Mesh

Implantation – Device

Implantation (Intramuscular Implantation Test)	
• 8 weeks • 13 weeks • 20 weeks • 52 weeks • 104 weeks	• PASS • PASS • PASS • PASS • PASS

The biologic and chemical characterization test results demonstrate that the subject device is biocompatible and there are no unexpected biologic findings resulting from the additional processing step of thermoforming the anatomical channel, nor are there any interactions between 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 the predicate device, Biodesign® Parastomal Hernia Graft (K162934). Completed performance testing on the subject device is listed in [Table 3](#).

Table 3: Performance Testing

Performance Test	
Substantial Equivalency Testing – Physical and Functional Characteristics	Physical Characteristics - Dimensional Measurements - Mesh Weave Characteristics - Pore Size - Determination of Device and Mesh Thickness - Weight per Unit Area (Areal Density) - Device Stiffness Functional Characteristics - Ball Burst Strength - Suture Pullout (Cross and Machine directions) - Tear Strength (Cross and Machine directions) - Tensile Strength (Cross and Machine directions)

Degradation Profile of the Mesh and Channel	- <i>In-vitro</i> Real-Time Degradation Study - <i>In-vitro</i> Accelerated Degradation Study
Design Validation Usability Testing	- IFU / Packaging / Labeling - Device Preparation - Insertion - Positioning/Placement - Fixation
Human Factors / Simulated Testing	- IFU - Packaging/Labeling - Device Preparation - Insertion - Positioning and Placement - Fixation

4. Animal Studies:

A comprehensive 4-week GLP Study evaluated the following objectives in a sub-chronic ileostomy using a swine model with simulated hernia defect repair to compare the subject device (Phasix™ ST Parastomal Hernia Mesh) to the predicate device (Biodesign® Hernia Graft, K162934) using the Sugarbaker Technique as a primary repaired hernia reinforcement device. Collectively, the data shows Phasix™ ST Parastomal Hernia Mesh is well tolerated in an intra-peritoneal Sugarbaker repair setting and performs in a biologically comparable manner to an established control mesh (Cook's Biodesign® Hernia Graft) at 4 weeks post-implantation. The results provide preclinical evidence supporting the intended use of the Phasix™ ST Parastomal Hernia Mesh for reinforcement in parastomal hernia repair.

5. Clinical Study:

A clinical study is not required in determining the safety and effectiveness of the subject device, Phasix™ ST Parastomal Hernia Mesh.

Conclusion:

Phasix™ ST Parastomal Hernia Mesh has the identical intended use and sterilization method as well as similar technological characteristics and principle of operation as both the predicate device and reference device.

Furthermore, the subject device has identical indications for use as the predicate device and identical materials of construction and manufacturing processes as the reference device.

Any differences in the technological characteristics between the subject device and the predicate or reference devices were thoroughly assessed and evaluated. All test results support that the subject device's safety, effectiveness and performance are similar to the predicate and reference devices. Therefore, Phasix™ ST Parastomal Hernia Mesh is substantially equivalent to Biodesign® Parastomal Hernia Graft (K162934).