June 12, 2019

C.R. Bard, Inc.
Shirin Mate
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K190185
Trade/Device Name: Phasix ST Mesh with Open Positioning System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWT, OOD, FTL
Dated: May 13, 2019
Received: May 14, 2019

Dear Shirin Mate:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For David Krause, Ph.D.
Acting Division Director
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190185

Device Name
Phasix ST Mesh with Open Positioning System

Indications for Use *(Describe)*
Phasix ST Mesh with Open Positioning System 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.

The open positioning system is intended to facilitate the placement, positioning and fixation of the mesh during open ventral hernia repair.

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 Mesh with Open Positioning System
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:

1.Submitter Information:

Davol Inc.,
C. R. Bard, Inc.
100 Crossings Boulevard
Warwick, RI 02886
Phone: (401) 825-8569
Fax: (401) 825-8765

Contact Person: Shirin Mate
Title: Regulatory Affairs Specialist
Email: **shirin.s.mate@crbard.com**

Date: June 6, 2019

2.Subject Device:

510(k) Type:	Traditional 510(k)
Trade Name:	Phasix™ ST Mesh with Open Positioning System
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Absorbable, Abdominal Hernia
Classification Panel:	General and Plastic Surgery
Regulatory Class:	Class II (Phasix™ ST Mesh with Open Positioning System)
	Class I (Open Positioning System Accessory)
Regulation Number:	21 CFR § 878.3300 (Phasix™ ST Mesh with Open Positioning System)
	21 CFR § 878.4800 (Open Positioning System Accessory)
Product Code:	OWT, OOD, FTL (Phasix™ ST Mesh with Open Positioning System)
	MDM (Open Positioning System Accessory)

3.Primary Predicate Device:

Name of Device:	K101920 - Ventrio™ ST Hernia Patch

Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric
Classification Panel:	General & Plastic Surgery
Regulatory Class:	Class II
Regulation Number:	21 CFR § 878.3300
Product Code:	FTL

4.Reference Device:

Name of Device:	K173143 - Phasix™ ST Mesh
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Absorbable, Abdominal Hernia
Classification Panel:	General and Plastic Surgery
Regulatory Class:	Class II
Regulation Number:	21 CFR § 878.3300
Product Code:	OWT, OOD, FTL, OWZ, OXC

5.Reference Device:

Name of Device:	K161424 - Phasix™ Mesh
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Film
Classification Panel:	General and Plastic Surgery
Regulatory Class:	Class II
Regulation Number:	21 CFR § 878.3300
Product Code:	OOD

6.Device Description:

Phasix™ ST Mesh with Open Positioning System is a sterile, single-use device for prescription use only. It is a bi-layer mesh comprised of Phasix™ ST Mesh (K173143, forms posterior layer) and Phasix™ Mesh (K161424, forms anterior layer) stitched together with a 10 mil P4HB monofilament. The combination of the two distinct layers forms a pocket to accommodate a preinserted removable accessory. The subject device is designed for reinforcement of soft tissue deficiencies during open ventral hernia repair. The subject device, predicate device and reference device have identical intended use for the mesh i.e. soft tissue repair/ reinforcement.

Open Positioning System

The removable open positioning system is an accessory with polypropylene (PP) handle attached to a Polytetrafluoroethylene (PTFE) guide. The accessory comes preinserted into the mesh pocket to aid with placement, positioning, and fixation. The center marking on the positioning guide will aid with proper centering and orientation over the defect. The accessory is removed following the initial fixation and then discarded. The intended use of the accessory is similar to the SorbaFlex Memory Technology utilized in the Ventrio™ ST Hernia Patch (K101920).

7.Indications for Use:

Phasix™ ST Mesh with Open Positioning System 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.

The open positioning system is intended to facilitate the placement, positioning and fixation of the mesh during open ventral hernia repair.

8.Technological Comparison to Predicate and Reference Devices:

The subject device, Phasix™ ST Mesh with Open Positioning System has the following similarities to the predicate and reference devices:

- The intended use of the mesh, i.e. for the repair / reinforcement of soft tissue, is identical to the Ventrio™ ST Hernia Patch (K101920), Phasix™ ST Mesh (K173143) and Phasix™ Mesh (K161424).
- The intended use of the open positioning accessory, i.e. to facilitate the ease of insertion, placement, positioning and fixation of the mesh, is similar to the SorbaFlex Memory Technology (PDO) utilized in the Ventrio™ ST Hernia Patch (K101920 with the exception of the removal of the open positioning accessory).
- The mesh and mesh materials are identical to the Phasix™ ST Mesh (K173143) and Phasix™ Mesh (K161424).
- The mesh pocket design is similar to the Ventrio™ ST Hernia Patch (K101920).
- The principle of operation for open ventral hernia repair is identical to the Ventrio™ ST Hernia Patch (K101920), Phasix™ ST Mesh (K173143) and Phasix™ Mesh (K161424)

with the exception of the open positioning accessory removal, i.e. insertion, placement/ positioning and fixation.

- The mesh sizes are within the similar range of the Ventrio™ ST Hernia Patch (K101920), Phasix™ ST Mesh (K173143) and Phasix™ Mesh (K161424).
- The base materials utilized in open positioning accessory, Polypropylene and PTFE are similar to the Polypropylene mesh material and PTFE monofilament sew line utilized in the Ventrio™ ST Hernia Patch (K101920).

The subject device, the Phasix™ ST Mesh with Open Positioning System incorporates following change as compared to the predicate and reference devices:

- It consists of a removable accessory instead of the embedded SorbaFlex Memory Technology (PDO) material as compared to Ventrio™ ST Hernia Patch (K101920). None of the cited predicate/reference devices consists of a removable accessory.

The subject device has similar intended use, indication for use, principle of operation, mesh materials/ manufacturing processes, packaging, sterilization (ethylene oxide) method and utilizes the same manufacturing facility. Any differences in the technological characteristics were thoroughly tested and the results demonstrate that there are no new questions of safety and effectiveness.

9.Performance Data:

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

Performance Standards

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

Biocompatibility Testing:

The biocompatibility evaluation for the Phasix™ ST Mesh with Open Positioning System 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*" June 16, 2016, 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 Phasix™ ST Mesh (K173143) and Phasix™ Mesh (K161424) and therefore considered safe and biocompatible. Thus, the tests specific to Phasix™ ST Mesh and Phasix™ Mesh were not repeated. However, in order to address any risks associated with interaction between the materials of the subject device mesh and the accessory (guide and handle), a biocompatibility testing was completed to demonstrate the subject device; Phasix™ ST Mesh with Open Positioning System is biocompatible for its intended use. Refer to Table 1.

Table 1: Biocompatibility Testing: Phasix™ ST Mesh with Open Positioning System

Test Method	**Results**
MEM Cell Cytotoxicity Elution	Pass
Intracutaneous Reactivity	Pass
Acute Systemic Toxicity	Pass
ISO Material Mediated Rabbit Pyrogenicity	Pass
Guinea Pig Maximization Test (Sensitization)	Pass
Material/ Chemical Characterization	Pass

The biocompatibility test results demonstrate that the subject device is biocompatible and there are no interactions between the subject device mesh and the accessory to affect its safety and effectiveness. Thus the subject device is safe and biocompatible for its intended use.

Electrical safety and electromagnetic compatibility (EMC)

The Phasix™ ST Mesh with Open Positioning System is not an electro-mechanical medical device nor is it medical system; therefore this section does not apply.

Software Verification and Validation Testing

The Phasix™ ST Mesh with Open Positioning System does not contain software therefore this section does not apply.

Product Testing

The performance test results demonstrate that subject device successfully met the established acceptance criteria and is substantially equivalent to the Ventrio™ ST Hernia Patch (K101920), Phasix™ ST Mesh (K173143) and Phasix™ Mesh (K161424). Performance testing completed on the subject device is listed in Table 2.

Table 2: Performance Testing - bench

Performance Testing- Bench	**Test Method**
Substantial equivalency testing	Mesh Pore Size (Major and Minor), Gel Disruption, Ball Burst, Tear Strength (Cross and Machine direction), Suture Retention Strength (Cross and Machine Direction).
Additional mechanical testing to evaluate features unique to the subject device.	15 Degree Recoil, Grip Strength, Pocket Integrity, Open Positioning System (accessory) removal force, Handle Attachment Strength, Three Tack Pluck.
Design Validation Usability Test.	Attributes: IFU, Insertion, Positioning and Placement, Fixation, Removal, Open Ventral Hernia Repair.

Animal studies:

A comprehensive 4 week GLP study in a porcine model was performed on the subject device as compared to Ventrio™ ST Hernia Patch (K101920) and Phasix™ ST Mesh (K173143) to evaluate the following:

- Mesh conformance
- Peritoneal tissue attachments (% area coverage and tenacity)
- Percentage of mesh contracture
- Histological evaluation of the host inflammatory/fibrotic response, vascular integration, Collagen deposition/remodeling and tissue ingrowth
- Mechanical tissue ingrowth properties via T-peel analysis

The subject device results were found to be comparable and therefore, Phasix™ ST Mesh with Open Positioning System is substantially equivalent to the Ventrio™ ST Hernia Patch (K101920) and Phasix™ ST Mesh (K173143). .

Clinical Study:

Clinical Study was not required in support of the subject device, Phasix™ ST Mesh with Open Positioning System.

Conclusion:

The subject device has similar intended use, indications for use, principle of operation, mesh technological characteristics, packaging materials/ components, manufacturing process and sterilization (ethylene oxide). Any differences in the technological characteristics between the subject device and the predicate/reference devices were assessed and evaluated. All test results provided in support of the subject device demonstrate safety and effectiveness similar to the predicate/reference devices. Therefore, Phasix™ ST Mesh with Open Positioning System is substantially equivalent to the predicate device, Ventrio™ ST Hernia Patch (K101920).