December 14, 2018

CR Bard Inc.
Shirin Mate
Regulatory Affairs Specialist
100 Crossing Boulevard
Warwick, Rhode Island 02886

Re: K182008
Trade/Device Name: Phasix ST Mesh with Echo 2 Positioning System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL, OWT, OOD, ORQ, GCJ
Dated: November 13, 2018
Received: November 14, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K182008

Device Name
Phasix™ ST Mesh with Echo 2™ Positioning System

Indications for Use *(Describe)*
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.

The Echo 2™ Positioning System is intended to facilitate the delivery and positioning of the mesh during laparoscopic 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.

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Phasix™ ST Mesh with Echo 2™ 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:

I. Submitter Information:

Davol Inc.,
C. R. Bard, Inc.
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Phone: (401) 825-8569
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Contact Person: Shirin Mate
Title: Regulatory Affairs Specialist
Email: **shirin.s.mate@crbard.com**

Date of submission: July 26th, 2018

II. Subject Device

510(k) Type:	Traditional 510(k)
Trade Name:	Phasix™ ST Mesh with Echo 2™ 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
Regulation Number:	21 CFR § 878.3300
Product Code:	OWT, OOD, FTL, ORQ, GCJ

III. Primary Predicate Device:

Name of Device:	Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294), cleared on May 1st 2017
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, ORQ, GCJ

IV. Secondary Predicate Device:

Name of Device:	Phasix™ ST Mesh (K173143) cleared on April 25th, 2018.
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

V. Device Description:

The Phasix™ ST Mesh with Echo 2™ Positioning System is a sterile single use mesh pre-attached to the Echo 2™ Positioning System. The subject device is a combination of the FDA cleared Phasix™ ST Mesh (K173143) and the Echo 2™ Positioning System that is cleared by the FDA in the Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294). The Echo 2™ Positioning System is removed following the mesh placement and fixation. As with the Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294), many sizes of the subject device include an introducer tool accessory.

The subject device is intended for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias and will utilize a positioning system to facilitate the delivery and positioning of the mesh during laparoscopic hernia repair.

Procedures involving "laparoscopic hernia repair" also pertain to those which are conducted under laparoscopic visualization through a trocar, such as robotic assisted laparoscopic ventral hernia repair (LVHR).

The Phasix™ ST Mesh in the subject device is a fully resorbable mesh with a resorbable hydrogel coating and is identical to the secondary predicate device, Phasix™ ST Mesh (K173143). It is co-knitted using Poly-4-hydroxybutyrate (P4HB) and Polyglycolic Acid (PGA) fibers to form two sided mesh. The PGA side of the mesh is coated with a bioresorbable, chemically modified sodium hyaluronate (HA), Carboxymethylcellulose (CMC) and Polyethylene Glycol (PEG) based hydrogel. The fascial P4HB side of the mesh allows for a prompt fibroblastic response through its interstices, allowing for complete tissue ingrowth, similar to P4HB mesh alone. The visceral PGA side of the mesh coated with a bioresorbable hydrogel separates the mesh from underlying tissues and organ surfaces to help minimize tissue attachment to the mesh. Shortly after hydration, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days.
Preclinical implantation studies indicate that resorption of the P4HB fibers is minimal throughout the 12 week expected healing period and up to 26 weeks post implantation. Significant degradation of the mesh fibers is observed in preclinical studies within 12 to 18 months, indicating loss in mechanical integrity and strength of the mesh. While fiber segments were observed at 18 months, they continued to degrade.

This Phasix™ ST Mesh (K173143) is preattached to the Echo 2™ positioning system on the hydrogel side of the mesh using nylon connectors. The Echo 2™ Positioning System is composed of nitinol wire, encased in a sealed nylon frame. A Polyethylene Terephthalate (PET) center hoisting suture is attached to the nylon frame. The Echo 2™ positioning system utilized in the subject device is identical in materials and construction to the Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294).Once inserted into the abdomen, the positioning system facilitates both deployment and positioning of the mesh. After initial fixation is complete, the Echo 2™ Positioning System is manually detached from the mesh and then removed from the body through a trocar or skin incision.

Device Accessories

The sterile stainless steel introducer tool (subject device accessory) is identical to the introducer tool utilized in Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294)

and will be included with the several sizes of the subject device. The introducer tool assists in rolling and introducing the subject device via the trocar into abdominal cavity.

VI.Indications for Use of Device:

The Phasix™ ST Mesh with Echo 2™ Positioning System is indicated as below:

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.
The Echo 2™ Positioning System is intended to facilitate the delivery and positioning of the mesh during laparoscopic hernia repair.

VII. Technological Comparison to Predicate Devices:

Comparison of the technological characteristics with the predicate devices:

- **Indications for use:** The indication for use of Phasix™ ST Mesh in subject device is identical to the indications for use of Phasix™ ST Mesh (K173143 with the exception of specific indication for hiatal hernia) and identical to the Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294 with exception of term "soft tissue prosthesis"). The indications for use of Echo 2™ Positioning System of subject device is similar to the Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294). The subject and predicate devices all have similar intended use i.e. reinforcement/ reconstruction of soft tissue deficiencies, such as repair of hernias.
- **Mesh component:** The Phasix™ ST Mesh utilized in subject device is identical to the PhasixTM ST Mesh (K173143). The subject and both predicate devices consists of identical PGA fibers in their mesh construct and an identical HA/CMC PEG based hydrogel layer adhered on the PGA side of the mesh. The placement of Echo 2™ positioning system for both the subject and primary predicate devices is on the hydrogel side of mesh.
- **Mesh Size**: The mesh sizes of the subject device, Phasix™ ST Mesh with Echo 2™ Positioning System are identical to the marketed mesh sizes of the Ventralight™ ST Mesh with Echo 2™ Positioning System. Similar mesh sizes are also currently marketed for the Phasix™ ST Mesh (K173143).

- **Positioning system:** The materials and construction of the Echo 2™ Positioning System utilized in the Phasix™ ST Mesh with Echo 2™ Positioning System are identical to the Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294). The Echo 2™ Positioning System sizes are similar between the subject and predicate device, as the subject device Echo 2™ Positioning System has been optimized to fit various sizes of Phasix™ ST Mesh.
- **Introducer tool:** Introducer tool utilized in Phasix™ ST Mesh with Echo 2™ Positioning System is identical to the introducer tool utilized in Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294).
- **Principle of Operation:** The principle of operation of Phasix™ ST Mesh with Echo 2™ Positioning System with respect to delivery, support, access/ fixation and removal is identical to the Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294).

The subject device has similar intended use, indications for use, principle of operation and similar technological characteristics with regards to design, materials, manufacturing processes, packaging and sterilization (EtO) as the primary and secondary predicate devices. The subject and the predicate devices all are manufactured at the same manufacturing facility.

VIII. 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 Echo 2™ 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 materials used in construction of the Phasix™ ST Mesh, Echo 2™ Positioning System and introducer tool are known to be biocompatible as demonstrated by their safe clinical use and successful clearance by the FDA under K173143 and K170294 respectively. Therefore, these tests were not repeated. However, in order to address any risks associated with the interactions between the Phasix™ ST Mesh and the Echo 2™ Positioning System, the subject device was evaluated using the following tests.

Following tests support the biocompatibility of the subject device:

1. Cytotoxicity
2. Pyrogenicity
3. Chemical Characterization.

The biocompatibility test results demonstrate that the subject device is biocompatible and there are no interactions between the Phasix™ ST Mesh and the Echo 2™ Positioning System to affect its safety and effectiveness.

Electrical safety and electromagnetic compatibility (EMC)

The Phasix™ ST Mesh with Echo 2™ 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 Echo 2™ Positioning System does not contain software therefore this section does not apply.

Product Testing

Phasix™ ST Mesh with Echo 2™ Positioning System passed all the test requirements and its test results demonstrated the substantial equivalence to the test results of the predicate devices. Performance and mechanical testing on the subject device included:

1. Mechanical testing of subject device:
    - Mesh Integrity (Gel Disruption)
    - Connector to mesh attachment strength
    - Ball Burst
2. Simulated use evaluations using bench top simulator:
    - Delivery
    - Support
    - Access/ Fixation

- Removal

3. Performance testing in porcine model
    - Delivery
    - Support
    - Access/ Fixation
    - Removal

All the samples of the subject device successfully met the established acceptance criteria and performed as intended and similar to the predicate devices.

Animal studies:

Since the Phasix™ ST Mesh in subject device is identical to the secondary predicate, Phasix™ ST Mesh (K173143), animal studies were not required to support the subject device.

Clinical Study:

Clinical study was not required in support of the subject device, Phasix™ ST Mesh with Echo 2™ Positioning System.

Conclusions:

The subject and predicate devices have similar intended use, indications for use, principle of operation and technological characteristics. All test results provided in support of the subject device demonstrate safety, effectiveness and performance similar to the predicate devices. Therefore, the subject device, Phasix™ ST Mesh with Echo 2™ Positioning System, is substantially equivalent to the primary predicate device, Ventralight™ ST Mesh with Echo 2™ Positioning System (K170294), and secondary predicate device, Phasix™ ST Mesh (K173143).