April 25, 2018

C. R. Bard Inc
Mr. Tony John
Senior Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K173143
Trade/Device Name: Phasix ST Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWT, OWZ, OXC, FTL, OOD
Dated: March 28, 2018
Received: March 29, 2018

Dear Mr. John:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

David Krause -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)*

K173143

Device Name
Phasix™ ST Mesh

Indications for Use *(Describe)*

The 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.

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

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:

Company Name:	Davol Inc., Subsidiary of C. R. Bard, Inc.
Company Address:	100 Crossings Boulevard Warwick, RI 02886
Telephone:	(401) 825-8692
Fax:	(401) 825-8765
Contact person:	Tony John, MS Sr. Regulatory Affairs Specialist
Date of Submission:	September 20, 2017

Subject Device Name:

Name of Device:	Phasix™ ST Mesh
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Absorbable, Abdominal Hernia
Regulatory Class:	Class II
Regulation Number:	878.3300
Product Code:	OWT, OOD, FTL , OXC, OWZ

Predicate Device:

Name of Device:	Gore® BioAbsorbable (Bio-A®) Mesh
510(k)#:	K033671
Common or Usual Name:	Bioabsorbablel Mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	Class II
Regulation Number:	878.3300
Product Code:	OWT, OWZ, OXC

Reference Predicate Device:

Name of Device:	Phasix™ ST Mesh
510(k)#:	K143380
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Absorbable, Abdominal Hernia
Regulatory Class:	Class II
Regulation Number:	878.3300

Product Code: OWT, OOD, FTL

Device Description:

The Phasix™ ST Mesh is a fully resorbable mesh with a resorbable hydrogel coating. It is a sterile mesh prosthesis designed for the reinforcement and reconstruction of soft tissue deficiencies. Phasix ™ ST Mesh is co-knitted using poly-4-hydroxybuterate (P4HB) and polyglycolic acid (PGA) fibers. P4HB is produced from a naturally occurring monomer and is processed into monofilament fibers and then knitted into a surgical mesh. P4HB degrades through a process of hydrolysis and a hydrolytic enzymatic digestive process. It has been developed to reinforce areas where weakness exists while minimizing the variability of resorption rate (loss of mass) and strength to provide support throughout the expected healing period. 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 observed in preclinical studies within 12 to 18 months indicates loss in mechanical integrity and strength. While fiber segments were observed at 18 months, they continued to degrade. Phasix™ ST Mesh is coated on the PGA surface with a resorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel. The fascial side of the mesh allows for a prompt fibroblastic response through the interstices of the mesh, allowing for complete tissue ingrowth, similar to P4HB mesh alone. The visceral side of the mesh is a resorbable hydrogel coating, separating 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.

Indications for Use of Device:

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.

Technological Comparison to Predicate Devices:

The proposed Phasix™ ST Mesh is identical in material and design to the predicate Phasix™ ST Mesh (K143380) and has comparable performance with the Gore Bio-A reference predicate. The proposed and predicate devices have the same intended use and similar indications for use statements.

The following technological differences exist between the subject and the primary predicate device:

- They are composed of different resorbable materials.
- They have minor difference in the following physical characteristics:
    - Mesh Thickness
    - Mesh Density
    - Mesh Thickness
- There are differences in the following performance characteristics:
    - Ball Burst Strength
    - Tear Strength
    - Resorption Profile

Where minor technological differences exist between the proposed and reference predicate device, testing demonstrates that the differences do not adversely affect the safety and performance of the proposed device.

Performance Data:

Since the proposed and reference predicate device are identical, the following biocompatibility and animal performance data are being leveraged from the K143380 510(k) submission in support of the substantial equivalence determination.

Biocompatibility Testing

The materials used in the construction of the Phasix™ ST Mesh are were evaluated with complete biocompatibility testing in accordance with FDA's Blue Book Memorandum #G95-1 issued on May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and FDA Guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process". The following studies were completed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Pyrogenicity
- Genotoxicity

- Local and Systemic Toxicity (4 and 13 week)
- Local Toxicity (4, 8, 13, and 20 week)

Animal Studies

In vivo porcine studies were performed to characterize the mechanical strength, tissue response, and resorption profile of the Phasix™ ST Mesh device at 4, 12, and 24 weeks.

Bench Testing

Bench testing was performed to compare the proposed Phasix™ ST Mesh to the cited predicate Gore® Bio-A® device. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" published March 2, 1999, the following physical and performance characteristics were evaluated:

- Mesh thickness
- Mesh density
- Mesh pore size
- Burst strength
- Mesh knit/weave characteristics
- Device stiffness
- Tear strength/resistance
- Suture pullout strength.

Electrical safety and electromagnetic compatibility (EMC)

There are no electrical or metal components in the Phasix™ Mesh; therefore the proposed device does not require EMC and Electrical Safety evaluation.

Software Verification and Validation Testing

The proposed Phasix™ Mesh does not contain software.

Clinical Study

Data and discussion from 2 separate retrospective clinical studies were included in this submission, demonstrating the safety and performance of the Phasix™ ST Mesh in hiatal hernia repair.

- A retrospective review of 50 consecutive patients who had a paraesophageal hernia repair with Phasix™ ST Mesh reinforcement of the crural closure at a single institution.

Demographics	Total	Female	Male
Patients	50	34 (68%)	16 (32%)
Mean Age	65 years		
Mean BMI	30.24 kg/m2		
BMI Range	17.1 kg/m2-41.5 kg/m2		

The following procedures were performed:

- Primary hiatal hernia repair
- Fundolipication
- Partial gastroectomy
- Collisgastrophy
- Relaxing incision

All patients either underwent objective follow-up (EGD & UGI) or non-objective follow-up at time points ranging from 3, 12, and 18 months. There was one small, asymptomatic recurrence and no mesh related complications or erosions.

- A retrospective review of 180 patients who underwent laparoscopic hiatal hernia repair with Phasix™ ST Mesh to reinforce the crural closure was performed at a single institution with multiple surgeons. This review included any patient who had Phasix™ ST Mesh used to reinforce the crural closure and included other concomitant procedures.

Demographics	Total	Male	Female
Patients	180	60 (33%)	120 (67%)
Median Age	66 years		
Preoperative Diagnosis			
Gastrointestinal Reflux (GERD)	59 (32.8%)		
Paraesophageal hernia (PEH)	120 (66.7%)		
Morgagni hernia	1 (0.5%)		
Comorbidity			
Steroid use or Diabetes Mellitus	22		
Operation			

First time	142 (78.9%)
Re-operation	38 (21.1%)
Median ASA Score	2

The following procedures were performed:

- Nissen fundoplication
- Partial (Toupet or Dor) fundoplication
- LINX implantation
- partial or total gastrectomy
- Collis gastroplasty
- Diaphragm relaxing incision

Objective follow-up was conducted in 84 patients with a median follow-up time of 4 months postoperatively. Esophagogastroduodenoscopy (EDG) was performed in 37 patients, barium swallow (BS) in 20 patients and both EGD and BS in 27 patients. There were 2 recurrent asymptomatic hernias identified in two patients. The first was identified in a patient by EDG during routine Collis gastroplasty follow-up and the second identified during percutaneous endoscopic gastrostomy (PEG) tube placement. The sizes of the hernias were 1-2 cm and 2-3 cm respectively and did not require any reintervention. This study did not observe any mesh related complications or mesh erosion.

Conclusions:

All test results provided in this submission demonstrate that the proposed Phasix™ ST Mesh is substantially equivalent to both the Gore® Bio-A® predicate and the Phasix™ ST Mesh reference predicate.