DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 5, 2015

C. R. Bard Incorporated
Mr. Tony John
Regulatory Affairs Specialist
100 Crossing Boulevard
Warwick, Rhode Island 02886

Re: K143380
Trade/Device Name: Phasix™ ST Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWT, OOD, FTL
Dated: November 24, 2014
Received: November 25, 2015

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143380

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.

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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BARD DAVOL INC. TECHNOLOGY TECHNIQUE TRAINING TRUST

510(K) SUMMARY

This 510(k) Summary is provided per the requirements of section 807.92(c).

Submitter Information:

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Submitter's Name:	Tony John, MS Regulatory Affairs Specialist
Date Summary Prepared:	June 4, 2015

Device Identification:

Trade Name:	Phasix™ ST Mesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Absorbable, Abdominal Hernia
Device Class:	Class II
Regulation Number:	21 CFR § 878.3300
Product Code:	OWT, OOD, FTL

Predicate Device Names:

- TephaFLEX® Mesh , K070894/K111946/K113723 (Tepha Inc), FDA cleared on: April 13, 2007, September 26, 2011, and February 15, 2012, respectively.
- Ventralight ST Mesh, K101851 (Davol Inc), FDA cleared on : July 15, 2010

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Device Description

The proposed 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

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.

Comparison of Technological Characteristics with the Predicate Device

The proposed Phasix™ ST Mesh has the same materials and design as the predicate TephaFlex® Mesh and Ventralight™ ST Mesh devices.

- The base mesh in the proposed Phasix™ ST Mesh is constructed of the same P4HB monofilament and knit pattern as the predicate TephaFlex® Mesh. The base mesh component of the predicate Ventralight™ ST Mesh is made of polypropylene.
- Both the proposed Phasix™ ST Mesh and predicate Ventralight™ ST Mesh contain a HA/CMC PEG based hydrogel. These devices also contain PGA fibers co-knit into the mesh to allow the

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hydrogel to adhere to the mesh. The purpose of the hydrogel coating is to minimize tissue attachment to the mesh. The TephaFLex® Mesh predicate does not contain a hydrogel coating or PGA fibers.

The proposed and predicate devices have the same intended use and similar indications for use statements. In addition, all three devices are sterilized via ethylene oxide and packaged in a Tyvek® envelope and foil pouch. Where minor technological differences exist between the proposed and predicate devices, testing demonstrates that the differences do not adversely affect the performance of the proposed device.

Performance Data:

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

Biocompatibility Testing

The materials used in the construction of the proposed Phasix™ ST Mesh are known to be biocompatible as demonstrated by their safe clinical use in the predicate devices. However, in order to address any risks associated with interactions between the three device components (i.e. P4HB, PGA, and the hydrogel coating), 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)

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.

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Bench Testing

Bench testing was performed to compare the proposed Phasix™ ST Mesh to the predicate TephaFlex® Mesh and Ventralight™ ST Mesh devices. 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 weave characteristics
- Mesh pore size
- Mesh density
- Mesh thickness
- Device stiffness
- Burst strength
- Tear resistance
- Suture pullout strength.

Additionally an in vitro degradation study was completed to demonstrate that the degradation of the PGA fibers and hydrogel coating present on the proposed Phasix™ ST Mesh construct do not impact the resorption profile of the P4HB mesh.

Animal Studies

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

Clinical Study

No clinical study was required in support of the Phasix™ ST Mesh.

Conclusion:

All test results provided in this submission demonstrate that the proposed Phasix™ ST Mesh is substantially equivalent to the cited TephaFlex® Mesh and Ventralight™ ST Mesh predicates.