DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 29, 2016

C.R. Bard, Inc.
Ms. Janna Babson
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K161424
Trade/Device Name: Phasix Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OOD
Dated: August 30, 2016
Received: August 31, 2016

Dear Ms. Babson:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161424

Device Name
Phasix™ Mesh

Indications for Use *(Describe)*
Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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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Section 5 510(k) Summary

I. SUBMITTER

Davol Inc.
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Date Prepared: May 16, 2016

II. DEVICE

Trade Name:	Phasix™ Mesh
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Film (21 CFR § 878.3300)
Regulatory Class:	Class II
Product Code:	OOD

III. PREDICATE DEVICE

Phasix™ Mesh cleared in K142818 on March 31, 2015.

IV. DEVICE DESCRIPTION

The proposed Phasix™ Mesh utilizes a fully resorbable poly-4-hydroxybutyrate (P4HB) polymer material. The P4HB is produced from a naturally occurring monomer, processed into monofilament fiber, and then knitted into a surgical mesh. Phasix™ Mesh is packaged individually as a sterile, single, flat mesh available in a wide range of shapes and sizes. Phasix™ Mesh provides immediate short-term support, and a scaffold that enables tissue in-growth over time while the mesh predictably and gradually degrades via hydrolysis and a hydrolytic enzymatic digestive process. Preclinical implantation studies indicate that Phasix™ Mesh retains approximately 70% of its strength at 12 weeks. Absorption of the mesh material is essentially complete within 12 to 18 months.

V. INDICATIONS FOR USE

Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

VI. SUMMARY COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Phasix™ Mesh has the same intended use as the predicate device. The following technological characteristics of Phasix™ Mesh are the same as the predicate device: device material, design, chemical composition, biocompatibility, packaging materials, and sterilization. The difference between the predicate and proposed devices arises in size availability. The proposed Phasix™ Mesh will be offered in 25 sizes in comparison to the 5 sizes currently marketed for the predicate Phasix™ Mesh (K142818).

The proposed Phasix™ Mesh has the same materials and design as the predicate Phasix™ Mesh. The proposed and predicate devices are constructed of the same P4HB monofilament knitted to create a mesh with the same weave characteristics. Both devices have the same indications for use, and are intended for use in the reconstruction and repair of soft tissue deficiencies where weakness exists such as hernia repair. In addition, the proposed device and the predicate device are packaged in the same materials including a DuPont™ Tyvek® envelope and foil pouch that undergo the same ethylene oxide sterilization method.

Table 5-1: Device Substantial Equivalence – General Characteristics

Device Features	Phasix™ Mesh (Proposed Device)	Phasix™ Mesh (Predicate device) K142818	Equivalency
Intended Use	Soft tissue reinforcement	Soft tissue reinforcement	Identical
Indication for Use	Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	Identical
Sterilization	Ethylene Oxide	Ethylene Oxide	Identical
Material	Poly-4-hydroxybutyrate (P4HB)	Poly-4-hydroxybutyrate (P4HB)	Identical
Structure	Knitted P4HB monofilament	Knitted P4HB monofilament	Identical

Device Features	Phasix™ Mesh (Proposed Device)		Phasix™ Mesh (Predicate device) K142818		Equivalency
Size and Shape	**Size**	**Shape**	**Size**	**Shape**	Similar
	3”	Circle	3”	Circle	
	4” x 6”	Rectangle	4” x 6”	Rectangle	
	6” x 8”	Rectangle	6” x 8”	Rectangle	
	8” x 10”	Rectangle	8” x 10”	Rectangle	
	10” x 12”	Rectangle	10” x 12”	Rectangle	
	4.5”	Circle			
	2.4” x 6.3”	Rectangle			
	3" x 3"	Square			
	3" x 6.3"	Rectangle			
	3" x 8"	Rectangle			
	4" x 4"	Square			
	4" x 8"	Rectangle			
	4" x 10"	Rectangle			
	6" x 10"	Rectangle			
	6" x 12"	Rectangle			
	8" x 8"	Square			
	8” x 12”	Rectangle			
	8" x 16"	Rectangle			
	10" x 16"	Rectangle			
	12" x 12"	Square			
	12" x 18"	Rectangle			
	14" x 14"	Square			
	16" x 16"	Square			
	18" x 18"	Square			
	19.5" x 19.5"	Square			
Packaging Type	Tyvek		Tyvek		Identical

VII. PERFORMANCE DATA

Performance Testing

Bench testing has been conducted in accordance with FDA’s *Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh* issued March 2, 1999 to evaluate the performance characteristics of proposed devices.

The following non-clinical tests were completed for the proposed and predicate device. The proposed Phasix™ Mesh demonstrated equivalent performance in comparison to the predicate device.

- Mesh thickness
- Mesh knit construction
- Mesh pore size
- Mesh density
- Tensile strength
- Device stiffness
- Suture pullout strength
- Burst strength
- Tear resistance

Biocompatibility testing

The proposed Phasix™ Mesh uses the same P4HB monofilament and the same processing aids as the predicate Phasix™ Mesh. Therefore, biocompatibility testing previously conducted on the predicate device (as presented via K142818) is also applicable to the proposed device, and thus is adopted in support of the proposed Phasix™ Mesh device. All testing conducted to date per the requirements of ISO 10993-1 indicates the device is biocompatible for its intended use as a permanent, tissue-contacting, implant device. Additional confirmatory LAL and cytotoxicity testing was performed.

Electrical safety and electromagnetic compatibility (EMC)

The Phasix™ Mesh is not an electro-mechanical medical device nor is it a medical system, therefore this section does not apply.

Software Verification and Validation Testing

The Phasix™ Mesh does not contain software; therefore this section does not apply.

Simulated Distribution Testing

Testing is to be performed in accordance with ASTM-D4169, *Standard Practice for Performance Testing of Shipping Containers and Systems*, in which the distribution environment that Phasix™ Mesh is routinely shipped in is simulated to demonstrate that the packaging system is able to maintain sterile package integrity.

Animal Study

In vivo studies were performed to characterize the mechanical strength and resorption profile of the P4HB monofilament mesh, and were originally provided in support of the predicate device (K142818). Since the proposed Phasix™ Mesh is constructed of the same P4HB monofilament knitted into a mesh with the same knit characteristics as the predicate device, these resorption studies are adopted in support of the proposed Phasix™ Mesh device, and were therefore not repeated.

Clinical Studies

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

VIII. CONCLUSIONS

The comparative analysis as well as the bench and preclinical testing results demonstrated that the Phasix™ Mesh has equivalent safety and performance as the predicate device that is currently marketed for the same intended use. Therefore, it is concluded that the proposed Phasix™ Mesh and the predicate device are substantially equivalent.