DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 23, 2016

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

Re: K162193
Trade/Device Name: Xenmatrix Ab Surgical Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: PIJ, FTM, OXH
Dated: November 28, 2016
Received: November 29, 2016

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" (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.

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,

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)*
K162193

Device Name
XenMatrix™ AB Surgical Mesh

Indications for Use *(Describe)*
The XenMatrix™ AB Surgical Graft is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including: abdominal plastic and reconstructive surgery; muscle flap reinforcement; hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias. The Rifampin and Minocycline coating has been shown in preclinical in vitro and in vivo testing to reduce or inhibit microbial colonization on the device. The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Davol Inc.
Subsidiary of C.R. Bard, Inc.
100 Crossings Blvd.
Warwick, RI 02886
(401) 463-7000

SECTION 7.0

510(k) Summary

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

Submitter Information:

Submitter's Name:	Tony John, MS Senior Regulatory Affairs Specialist
E-mail:	Tony.John@crbard.com
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
Date Summary Prepared:	August 3, 2016

Device Identification:

Trade Name:	XenMatrix™ AB Surgical Graft
1150608, 1150816, 1151530, 1152040, 1152530, 1152540, 1153030, 1153045	
Common/Usual Name:	Surgical Mesh
Classification Name:	Collagen Surgical Mesh Containing Drugs
Device Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	PIJ, FTM, OXH

Predicate Device Names:

The predicate device for this submission is XenMatrix™ AB Surgical Graft (K133223 and K151177); marketed by C. R. Bard, Inc. This predicate has not been subject to a design-related recall.

The reference device XenMatrix™ Surgical Graft (K140501) is used in this submission.

Davol Inc.
Subsidiary of C.R. Bard, Inc.
100 Crossings Blvd.
Warwick, RI 02886
(401) 463-7000

Device Description:
The XenMatrix™ AB Surgical Graft is an acellular, sterile, non-pyrogenic porcine dermal matrix for use in the reconstruction of soft tissue deficiencies. The graft is packed dry and must be hydrated prior to use.

Product sizes when hydrated are:

- 6x8 cm
- 8x16 cm
- 15x30 cm
- 25x30 cm
- 20x40 cm
- 25x40 cm
- 30x30 cm
- 30x45 cm

The proposed XenMatrix™ AB Surgical Graft surfaces are coated with an antimicrobial coating, which is comprised of a bioresorbable L-tyrosine succinate polymer and antimicrobial agents Rifampin and Minocycline. The coating is shaded orange in color due to the color of the antimicrobial agents.

Intended Use:
The XenMatrix™ AB Surgical Graft is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including: abdominal plastic and reconstructive surgery; muscle flap reinforcement; hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias. The Rifampin and Minocycline coating has been shown in preclinical in vitro and in vivo testing to reduce or inhibit microbial colonization on the device. The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

The Indications for Use statement for the subject device is identical to the predicate device. Both the subject and predicate devices have the same intended use.

Comparison of Technological Characteristics With the Predicate Device
The proposed XenMatrix™ AB Surgical Graft that is the subject of this submission remains the same as the previous version of this device. The addition of 8 new product sizes has no impact to the XenMatrix AB Surgical Graft technological properties, safety, or performance of the existing XenMatrix AB device. Specifically the proposed device has the same; material, biocompatibility, packaging materials and sterilization as the currently cleared product. The cited predicate device size ranges from 6x6cm to 19x35cm. The reference predicate ranges from 6x6 to 30x45cm. The proposed device size range (as descrbied in the table above) is within the size range of the existing cited and reference predicates.

Davol Inc.
Subsidiary of C.R. Bard, Inc.
100 Crossings Blvd.
Warwick, RI 02886
(401) 463-7000

Performance Data:

The following performance data is provided in support of the 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 subject device is comprised of identical materials, processed by identical manufacturing methods, and has the same contact and duration as the cited predicate. Therefore, the biocompatibility testing provided provided in the predicate (K133223) submission is being leveraged for the proposed device. The biocompatibility testing previously provided was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Electrical safety and electromagnetic compatibility (EMC)

The subject device 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 subject device does not contain software; therefore this section does not apply.

Product Testing

The following non-clinical tests were completed for the subject and predicate device. The subject device passed all the test requirements and demonstrated substantial equivalence to the test results of the predicate device.

- Performance and Functional testing of the proposed XenMatrix™ AB Surgical Graft
  - Phycial Characteristics
    - Device Thickness
    - Device (Flexural) Stiffness

Davol Inc.
Subsidiary of C.R. Bard, Inc.
100 Crossings Blvd.
Warwick, RI 02886
(401) 463-7000

- Funtional Characterisitcs
  - Burst Strength
  - Suture Pullout Strength
  - Tear Resistance
- Analysical Testing
  - Drug Content
  - Drug Impurities

All samples tested met the established acceptance criteria.

Animal Study

The animal study data was not required to demonstrate substantial equivalence.

Clinical Studies

Clinical studies were not performed for the submission of this subject device nor were clinical studies performed for the predicate device.

Conclusion:

The proposed XenMatrix™ AB Surgical Graft maintains the same safety and performance as that of the previously cleared XenMatrix™ AB device. The proposed XenMatrix™ AB Surgical Graft has the same intended uses and the same indications, technological characteristics, and principles of operation as the previously cleared XenMatrix™ AB (K133223 and K151177). Additional bench testing adequately demonstrates that the proposed XenMatrix™ AB Surgical Graft has equivalent performance as the previously cleared version of the device. Thus, the XenMatrix™ AB Surgical Graft is substantially equivalent to the cited predicate device.