



Food and Drug Administration  
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August 3, 2016

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

Re: K151177  
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: April 30, 2015  
Received: May 1, 2015

Dear Mr. John:

This letter corrects our substantially equivalent letter of July 30, 2015.

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

510(k) Number *(if known)*

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.

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## 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

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Date Summary Prepared: July 1, 2015

### **Device Identification:**

Trade Name: XenMatrix™ AB Surgical Graft  
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:**

C.R. Bard's XenMatrix™ AB Surgical Graft (K133223)

### **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 in sterile saline prior to use.

Product sizes when hydrated are:

- 6 x 6 cm
- 6 x 10 cm
- 6 x 16 cm
- 8 x 8 cm
- 10 x 10 cm
- 10 x 15 cm
- 15 x 20 cm
- 19 x 28 cm
- 19 x 35 cm
- 10 x 20 cm
- 20 x 20 cm
- 20 x 25 cm
- 10 x 28 cm
- 15 x 25 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.

#### **Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:**

The version of the device that is the subject of this submission remains that same as the previous version of this device with minor modifications in shelf life specification to allow for an extension of the current shelf life to 12 months. These minor modifications do not alter the safety or performance profile of the device, as demonstrated via the performance testing summarized below.

In addition to the above, device specifications have also been updated in efforts to more accurately characterize this device and its intended use.

#### **Performance Data:**

##### Previous Performance Data

Bench, biocompatibility, animal, and drug characterization testing was provided in the previous K133223 submission. This previous testing data remains valid for the current

submission since there are no manufacturing or technological changes between the proposed device and the previous (K133223) version of this device

In addition to the previous testing, additional bench testing was completed to demonstrate that any modifications that have been made to the XenMatrix AB device specifications have not adversely impacted the performance of the proposed device.

#### Animal data

Two *in vivo* dorsum-implanted rabbit infection model studies were performed to demonstrate that the revised specifications do not adversely impact the performance characteristics of the XenMatrix AB Surgical Graft. Devices were inoculated with bacteria at implantation, and at 7 days, post-implantation, bacterial colonization quantifications were conducted. At that time point the antimicrobial coating on the XenMatrix™ AB was observed to prevent bacterial colonization of the device.

The relevance of these studies to human clinical performance outcomes has not been demonstrated.

The correlation of these studies has not been demonstrated to be predictive of positive human clinical outcomes.

#### Human clinical data

None.

The claim of reduction of colonization has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

#### **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). Additional animal studies demonstrate 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.