Davol Inc.
Subsidiary of C.R. Bard, Inc.
100 Crossings Blvd.
Warwick, RI 02886
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BARD DAVOL INC. | TECHNOLOGY TECHNIQUE TRAINING TRUST

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 2 8 2014

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

Submitter Information:

Submitter's Name:	Tony John, MS Regulatory Affairs Specialist
Company Name:	Davol Inc., Subsidiary of C. R. Bard, Inc.
Company Address:	100 Crossings Boulevard Warwick, RI 02886
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Date Summary Prepared:	April 8, 2014

Device Name:

Trade Name:	XenMatrix™ Surgical Graft
Product Code:	FTM
Classification Name:	Mesh, Surgical
Regulation Number:	21 CFR 878.3300
Device Class:	II
Panel:	General & Plastic Surgery

Predicate Device:

K081272 "Porcine Dermal Matrix Surgical Mesh" FDA cleared on 31 July 2008 from Brennen Medical, LLC . Davol, Inc. acquired the 510(k) product line in June 2009 and listed it as XenMatrix™ Surgical Graft.

Device Descriptions:

XenMatrix™ Surgical Graft is an acellular, sterile, non-pyrogenic porcine dermal matrix packed hydrated in sterile saline for use in the reconstruction of soft tissue deficiencies.

Intended Use:

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.

Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Uses:

The XenMatrix™ Surgical Graft has the same intended use and fundamental scientific technology as the predicate device. The following technological characteristics of the XenMatrix™ Surgical Graft are the same as the predicate device: material, biocompatibility, and sterilization.

The difference between the predicate device and the proposed device is the proposed device has larger sizes and smaller sizes than the currently cleared predicate. Performance testing demonstrates that these differences do not adversely affect the safety and effectiveness of the proposed device.

Davol has also conducted a risk analysis to address the potential clinical risks that are associated with meshes that are larger than our previously cleared sizes. Based on our analysis and the results of our validation testing Davol does not expect any different clinical risks due to the larger mesh sizes being proposed.

Summary of Non-Clinical Testing:

Bench and pre-clinical testing was performed on the XenMatrix™ Surgical Graft to support substantial equivalence. Bench testing on the proposed device included burst strength, tensile strength, and suture retention strength. Packaging testing included seal strength and ship testing. Pre-clinical testing includes histology examination. Results of testing demonstrate that the XenMatrix™ Surgical Graft of the expanded sizes meets the same product specifications and intended uses.

Statement of Equivalence:

The test results and risk analysis provided in this submission support the safety and effectiveness of the device for its intended use and demonstrate that the proposed device is substantially equivalent to its predicate devices.

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

April 28, 2014

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

Re: K140501
Trade/Device Name: XenMatrix™ Surgical Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OWV, OXH
Dated: April 9, 2014
Received: April 10, 2014

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K140501

Device Name: XenMatrix™ Surgical Graft

Indications for Use:

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.

Prescription Use ✓ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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