DEC 1 3 2013

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

AUGUST 27, 2013

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

Submitter Information:

Submitter's Name:	Davol, Inc., Subsidiary of C. R. Bard, Inc.
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Device Name:

Trade Name:	Bard® Ventralex™ Hernia Patch
Common/Usual Name:	- Surgical Mesh
Classification Name:	- Mesh, Surgical, Polymeric
Classification Code:	- Class II, § 878.3300, Product Code FTL

Predicate Device Names:

- Bard® Ventralex™ Hernia Patch,
  - K021736 (Davol, Inc.), FDA cleared on 07/16/2002
  - K024008 (Davol, Inc.), FDA cleared on 02/20/2003
- Bard® Ventrio™ Hernia Patch,
  - K081777 (Davol, Inc.), FDA cleared on 09/29/2008
  - K100229 (Davol, Inc.), FDA cleared on 04/21/2010

Device Description:

The proposed Ventralex Hernia Patch is a self-expanding, sterile prosthesis, containing two primary layers of polypropylene mesh stitched with polytetrafluoroethylene (PTFE) monofilament to an expanded polytetrafluoroethylene (ePTFE) sheet. The mesh component is non-absorbable; however, the device contains a fully absorbable recoil ring using SorbaFlex™ Memory Technology, an absorbable polydioxanone (PDO) monofilament.

The mesh is constructed from knitted polypropylene monofilament and forms a strong, porous, support material. The top layer of mesh has a mesh strap and forms a positioning pocket with the second mesh layer. The propylene mesh side promotes tissue in-growth and repairs the defect. The strap and pocket facilitate placement, positioning and fixation of the device. For a reference point, the small Ventralex Hernia Patch is constructed with a depth marker on the positioning strap. The depth marker is polypropylene monofilament dyed with a blue colorant to indicate the position of the device relative to the end of the laparoscopic trocar sleeve. After fixation to the abdominal wall, excess positioning strap material above the fixation line and at the level of the fascia is cut off and discarded.

A layer of ePTFE is stitched with PTFE monofilament thread and edge heat sealed to the polypropylene mesh. The ePTFE layer minimizes tissue attachment to the device. The SorbaFlex Memory Technology is comprised of an absorbable PDO monofilament welded to form a ring. The PDO monofilament recoil ring provides memory and stability to the device, facilitating ease of initial insertion, proper placement, and fixation of the device. The PDO monofilament fully degrades by means of hydrolysis *in vivo* in 6 – 8 months. The PDO monofilament ring is placed within a mesh tube constructed from a knitted polypropylene monofilament. The purpose of the mesh tube is to contain the PDO monofilament recoil ring during the degradation process.
Intended Use:

The Ventralex Hernia Patch is intended for use in all forms of hernia repair requiring reinforcement with a non-absorbable support material. The small Bard Ventralex Hernia Patch (4.3 cm / 1.7") is also intended to repair soft tissue deficiencies, including deficiencies caused by trocars.

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

The proposed Ventralex™ Hernia Patch has the same indications for use, technological characteristics, and performance characteristics as the original Ventralex Hernia Patch, cleared via K021736 and K024008, with the exception of the material type of the recoil ring and the containment mesh tube in which it is encased.

In this submission, Davol proposes modifying the material type of the recoil ring used in the Ventralex Hernia Patch. In the proposed device, the non-absorbable PET recoil ring will be replaced with an absorbable PDO monofilament recoil ring encased in a containment mesh tube The proposed PDO monofilament ring and containment mesh tube are identical to the PDO monofilament ring and containment mesh tube used in the previously cleared Ventrio Hernia Patch (K081777/K100229).

Performance Data:

Biocompatibility testing previously conducted for the Ventrio Hernia Patch (as presented via K081777) is also applicable to the proposed device and thus will not be repeated. All testing conducted to date (as per the requirements of ISO 10993) indicate that the device is biocompatible as per its intended use.

Bench testing results and in vivo simulated use experiments demonstrate that the proposed device design meets product specifications and intended uses In support of this submission, the proposed Ventralex Hernia Patch was deployed in a laparoscopic deployment model to evaluate the integrity of the PDO monofilament recoil ring and mesh tube when in a folded position. Additionally, the proposed Ventralex Hernia Patch underwent bench testing to ensure that the device recoiled to a flat position after folding. Whole system simulated use testing was conducted in an animal model to ensure that the proposed Ventralex Hernia Patch met key user needs. In vivo and in vitro resorption studies were performed and provided in support of the Ventrio Hernia Patch via K081777. These resorption studies were adopted for the proposed Ventralex Hernia Patch.

All test results 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 predicates.

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

C.R. Bard Incorporated
Ms. Mariya Buharin
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

December 13, 2013

Re: K132441
Trade/Device Name: Bard® Ventralex™ Hernia Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: November 15, 2013
Received: November 18, 2013

Dear Ms. Buharin:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For 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): Not known

Device Name: **Bard® Ventralex™ Hernia Patch**

The Bard® Ventralex™ Hernia Patch is intended for use in all forms of hernia repair requiring reinforcement with a nonabsorbable support material. The small Bard® Ventralex™ Hernia Patch (4.3 cm / 1.7") is also intended to repair soft tissue deficiencies, including deficiencies caused by trocars.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (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)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132441