MAR 2 3 2011

Section 8.0 510(k) Summary of Safety and Effectiveness

A. Submitter Information

Submitter's Name:	Davol Inc.
Address:	Subsidiary of C.R. Bard, Inc. 100 Crossings Boulevard Warwick, RI 02886
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Contact Person:	Michelle Godin
Date of Preparation:	July 8, 2010

B. Device Name

Trade Name:	**Bard** Ventrio ST Hernia Patch
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh, Polymeric

C. Predicate Device Name

Trade name:	Ventrio Hernia Patch (Davol Inc.) K100229, K081777
Trade name:	Sepramesh IP Mesh (Davol Inc.) K040868, K053066, K063739

D. Device Description

The proposed device, Ventrio ST Hernia Patch, is a self-expanding bioresorbable coated, partially absorbable, sterile prosthesis, containing 2 distinct layers stitched with PTFE monofilament, forming a positioning pocket. The top layer is knitted polypropylene mesh, 0.004" in monofilament diameter, and the bottom layer is Sepramesh IP Mesh. Sepramesh IP Mesh is co-knitted using polypropylene (PP) and polyglycolic acid (PGA) fibers to result in a two-sided mesh with a PP surface and a PGA surface. The mesh is coated on the PGA surface with a bioresorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel. The fascial side of the mesh allows a prompt fibroblastic response through the interstices of the mesh, allowing for tissue ingrowth into the mesh. The visceral side of the mesh is a

bioresorbable coating, separating the mesh from underlying tissue and organ surfaces to minimize tissue attachment to the mesh. Shortly after placement, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days.

The device contains Sorbaflex Memory Technology, which provides memory and stability to the device, facilitating ease of initial insertion, proper placement, and fixation of the device. The Sorbaflex Memory Technology is comprised of an extruded polydioxanone (PDO) monofilament that is contained within a knitted polypropylene mesh tube. The extra large oval size patches contain two separate Sorbaflex PDO monofilaments. The Sorbaflex PDO monofilament fully degrades in vivo by means of hydrolysis. Absorption is essentially complete in 6-8 months.

E. Intended Use

The proposed device, Ventrio ST Hernia Patch, is a sterile, single use device indicated for use in the reconstruction of soft tissue deficiencies, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias. The intended use for the proposed device, Ventrio ST Hernia Patch, is the same as the predicate devices, Ventrio Hernia Patch and Sepramesh IP Mesh.

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

The proposed device, Ventrio ST Hernia Patch, has the same design as the currently marketed Ventrio Hernia Patch (K100229) with the exception of the posterior polypropylene mesh layer and the single layer of expanded polytetrafluoroethylene (ePTFE). These two layers have been replaced by Sepramesh IP Mesh which is a co-knitted polypropylene/PGA mesh with a bioresorbable coating. The anterior polypropylene slit mesh and PDO monofilament ring contained within a knitted tube mesh are the same as the predicate device, Ventrio Hernia Patch, as well as the interlocking stitch using polytetrafluoroethylene (PTFE) monofilament to sew the patch. The Sepramesh IP Mesh

used in the proposed device is exactly the same as the currently marketed device, Sepramesh IP Mesh.

Laboratory bench testing was performed to verify that the proposed device's performance characteristics are similar to that of the predicate devices.

G. Performance Data

Bench testing was performed to assess the effects of the new characteristics of the proposed device, Ventrio ST Hernia Patch. The tests compared the proposed device against the predicate devices, Ventrio Hernia Patch and Sepramesh IP Mesh. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" (March 2, 1999), the tests included physical characteristics including mesh weave, mesh pore size, device density, device thickness, device stiffness as well as performance evaluations including burst strength, suture pullout strength, PDO ring weld tensile strength, PGA pullout strength, dry bond strength, mass/area measurements, and deployment/hydrogel disruption testing. In addition, two preclinical studies were performed. An overall performance study in pigs was performed to evaluate peritoneal tissue attachment, percent area coverage, mesh contracture, tissue ingrowth, and host inflammatory/fibrotic response. An in vivo degradation study was performed in rats to evaluate the host inflammatory/fibrotic response and absorption characteristics of the bioresorbable coating, PGA fibers, and the PDO monofilament during degradation of the material in vivo. The testing presented in this submission demonstrates that the proposed device, Ventrio ST Hernia Patch, is substantially equivalent to the predicate devices. The results of the testing can be found in Section 16.

Biocompatibility testing in accordance with the ISO 10993 standards was conducted. The results indicate that the device is biocompatible per these standards. Results are summarized in Section 15 and copies of the test reports are in Attachment 3.

The results demonstrate that the proposed device is substantially equivalent to the currently marketed predicate devices and therefore, the proposed device, Ventrio ST Hernia Patch, is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

C.R. Bard, Inc.
% Ms. Michelle Godin, MS, RAC
Regulatory Affairs Project Manager
100 Crossings Boulevard
Warwick, Rhode Island 02886

MAR 2 3 2011

Re: K101920
Trade/Device Name: Ventrio ST Henria Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 11, 2011
Received: March 14, 2011

Dear Ms. Godin:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Ventrio ST Hernia Patch

Indications for Use:

The Ventrio ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, including repair of hernias.

Prescription Use ___X___ 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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101920