APR 21 2010

K100229

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8. 510(k) Summary

510(k) SUMMARY

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

510(k) Number:	TBD
Owner Name:	Davol Inc., Subsidiary of C. R. Bard, Inc.
Address:	100 Crossings Boulevard Warwick, RI 02886
Contact Person:	Michelle Godin Regulatory Affairs Associate Tel: 401-825-8589 Fax: 401-825-8765 Email address: michelle.godin@crbard.com
Alternate Contact:	Thomas Hutchinson Vice President, Quality Assurance, Regulatory and Clinical Affairs Tel: 401-825-8409 Fax: 401-825-8765 Email address: tom.hutchinson@crbard.com
Date Prepared:	January 25, 2010
Device Trade Name:	Ventrio Hernia Patch
Device Common Name:	Surgical Mesh
Class:	Class II, 21 CFR 878.3300, Product Code FTL

Predicate Device(s):

- Ventrio Hernia Patch (K081777)

Device Description:

The Ventrio Hernia Patch is a sterile, single use device indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias. This device contains two primary layers of monofilament polypropylene mesh stitched with PTFE

monofilament to an ePTFE sheet to form a positioning pocket. The device also contains an absorbable recoil ring using AbsorbaFlex Memory Technology, which provides memory and stability to the device and facilitates ease of initial insertion, proper placement, and fixation of the device. The AbsorbaFlex Memory Technology is comprised of an absorbable polydioxanone (PDO) monofilament, which fully absorbs in vivo between 6-8 months. The polydioxanone monofilament is dyed violet using D & C Violet No. 2.

Indication for Use:

The Ventrio Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.

Comparison to Predicate Devices:

The Ventrio Hernia Patch has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the Ventrio Hernia Patch are the same as the predicate device including packaging, biocompatibility, sterilization, and labeling. The technological characteristics include polypropylene mesh layers to allow for tissue in-growth, an ePTFE layer to minimize tissue attachment, and a PDO monofilament ring to provide stability to the device. Two minor differences exist between the predicate device and the proposed device. The first difference is that the anterior polypropylene slit mesh layer for all product sizes is now constructed of a lighter weight, larger pore knitted polypropylene monofilament which is identical in the polypropylene material composition. The knitted polypropylene monofilament differs in diameter (.006 in to .004 in) and knit design (pore size and knit pattern) only. The second difference is that the PDO monofilament ring is contained within a knitted polypropylene mesh tube for the 4 larger sizes while the PDO monofilament ring is contained between two stitched layers of knitted polypropylene mesh for the small sizes. The purpose of the containment mesh is to contain the PDO ring during the degradation process; there is no difference in functionality of the polypropylene mesh tube versus the two stitched layers of knitted mesh. The knitted polypropylene mesh tube and the two stitched layers of knitted polypropylene mesh are the same material composition and only differ in

monofilament diameter (.006 in to .005 in) and knit design (pore size and knit pattern). Where minor technological differences exist between the proposed device and the predicate device, performance testing demonstrates that these differences do not adversely affect the safety and effectiveness of the proposed device.

Summary of Non-Clinical Testing:

Bench testing and animal studies were performed on the Ventrio Hernia Patch to support substantial equivalence. Bench testing on the proposed device included linear verification, visual inspections, recoil testing, ball burst strength testing, suture pullout testing, laparoscopic deployment testing, PDO containment testing, and mesh/fixation holding strength. Predicate device testing included PDO weld and monofilament testing, seal strength testing, package qualification testing, and biocompatibility testing as there were no PDO, packaging, or material changes to the device. A 4 week post-implantation study in a porcine model was completed on the predicate device and proposed device to evaluate tissue attachment, mesh contracture, tissue in-growth, and host inflammatory and fibrotic response for both devices. Results of testing demonstrate that the Ventrio Hernia Patch design meets product specifications and intended uses.

Statement of Equivalence:

The Ventrio Hernia Patch has the same indications for use and technological characteristics as the predicate device. Based on this and the design and engineering data provided in the Premarket Notification, the proposed Ventrio Hernia Patch has been shown to be substantially equivalent to the cleared Ventrio Hernia Patch.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

APR 21 2010

C.R. Bard, Inc.
% Davol, Inc.
Ms. Michelle Godin, MS, RAC
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K100229
Trade/Device Name: Ventrio Hernia Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 19, 2010
Received: March 22, 2010

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.

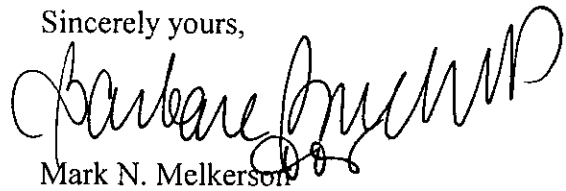
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K100229

7. Statement of Indications for Use

Indications for Use

510(k) Number (if known):

Device Name: Ventrio Hernia Patch

Indications for Use:

The Ventrio Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.

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)

for DXK

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

510(k) Number K100229