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SEP 2 9 2008

SECTION 7.0 510(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
Telephone:	(401) 825-8588
Fax:	(401) 825-8765
Contact Person:	Stephanie Baker
Date of Preparation:	June 20, 2008

B. Device Name

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

C. Predicate Device Name

Trade name:	Bard Composix Kugel Hernia Patch* (Davol Inc.) (K061314); Ethicon PROCEED Ventral Patch (K061533); W.L. Gore INFINIT Mesh (K081069) and DualMesh® EMERGE PLUS Biomaterial (K022782).

D. Device Description

The proposed Ventrio Hernia Patch is a self-expanding, sterile prosthesis, containing two primary layers of 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 AbsorbaFlex Memory Technology, an absorbable polydioxanone (PDO) monofilament. The AbsorbaFlex Memory Technology's PDO monofilament ring provides memory and stability to the device, facilitating ease of initial insertion, proper placement, and fixation of the device.

* The Ventrio Hernia Patch is substantially equivalent to the modified Bard Composix Kugel Hernia Patch containing the re-designed recoil ring covered under 510(k) K061314, cleared on June 2, 2006

The mesh component of the device is constructed of knitted polypropylene monofilament approximately 0.006" in diameter. The AbsorbaFlex PDO monofilament ring is 0.038" in diameter. It has two donut-shaped layers of knitted polypropylene monofilament mesh 0.006" in diameter on each side of the ring. These layers of mesh are stitched together around the ring using PTFE monofilament. The extra large oval sized patches contain inner and outer PDO monofilament rings. A single layer of expanded ePTFE is attached to the bottom primary layer of polypropylene mesh (posterior mesh). The attachment is accomplished with an interlocking stitch using PTFE monofilament. The peripheral edge of the polypropylene mesh will be heat sealed to the ePTFE layer.

E. Intended Use

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. The intended use for the Ventrio Hernia Patch is the same as the predicate device, Bard Composix Kugel Hernia Patch*, with the exception of the indication for repair of chest wall defects.

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

The proposed Ventrio Hernia Patch has the same intended use, and both similar and different technological characteristics as the currently marketed Bard Composix Kugel Hernia Patch (K061314), containing the re-designed recoil ring. The differences in the proposed device include a different material for the absorbable recoil mechanism (ring), and additional mesh layers around the recoil ring as compared with the predicate device.

Both the proposed device and the predicate Bard Composix Kugel Hernia Patch ("predicate Bard") device contain two layers of mesh constructed of knitted polypropylene monofilament. The predicate Ethicon PROCEED Ventral Patch also contains polypropylene mesh (K061533) ("predicate Ethicon PROCEED"). In addition, both the proposed and the predicate Bard devices also contain a single layer of expanded polytetrafluoroethylene (ePTFE) attached to the polypropylene mesh. In both devices, the ePTFE is attached to the polypropylene mesh with an interlocking stitch using polytetrafluoroethylene (PTFE) monofilament. The peripheral edge of the polypropylene mesh is heat sealed to the ePTFE layer in both the predicate and proposed devices. The predicate W.L. Gore INFINIT Mesh (K081069) and DualMesh® EMERGE Plus Biomaterial (K022782) devices also contain an ePTFE mesh.

* The Ventrio Hernia Patch is substantially equivalent to the modified Bard Composix Kugel Hernia Patch containing the re-designed recoil ring covered under 510(k) K061314, cleared on June 2, 2006

Both the proposed device and the predicate Bard device contain polymer rings as a recoil mechanism, to ensure stability and simplicity in proper patch placement. However, the proposed device uses a fully absorbable polymer ring composed of an absorbable polydioxanone monofilament, while the ring in the predicate Bard device is a permanent polymer ring composed of extruded monofilament polyethylene terephthalate (PET). The predicate Ethicon PROCEED also includes absorbable polymer rings. In the both the proposed and predicate Bard devices, the mesh surrounding either side of the recoil ring is stitched using PTFE sewing monofilament thread. However, in the small sizes of the predicate Bard device, the mesh on both sides of the ring is ultrasonically welded in addition to being stitched with PTFE sewing monofilament thread.

The proposed device also has additional mesh layers surrounding the recoil ring. Specifically, the absorbable polymer ring has two donut shaped layers of knitted polypropylene monofilament mesh on each side of the ring stitched together with PTFE monofilament thread. These donut shaped layers of mesh are not present in the predicate Bard device.

Laboratory bench testing and in vitro and in vivo resorption studies were performed to verify that the proposed product's performance characteristics are similar to that of the predicate device.

G. Performance Data

Laboratory bench testing was performed to compare the proposed Ventrio Hernia Patch to the currently marketed Bard Composix Kugel Hernia Patch*. In addition, in-vitro and in-vivo resorption studies were also performed on the proposed device to characterize the mechanical strength and resorption of the PDO monofilament. The results show that the proposed device is as safe and effective for its intended use as the currently marketed predicate device. Therefore, based on laboratory testing and the in-vitro and in-vivo resorption data, the proposed device is substantially equivalent to the predicate device.

* The Ventrio Hernia Patch is substantially equivalent to the modified Bard Composix Kugel Hernia Patch containing the re-designed recoil ring covered under 510(k) K061314, cleared on June 2, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Stephanie Baker
Senior Regulatory Affairs Associate
C.R. Bard, Incorporated
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K081777
Trade/Device Name: Ventrio Hernia Patch
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: September 11, 2008
Received: September 12, 2008

Dear Ms. Baker:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K061777

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 for the 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)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K061777