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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

JUL 20 2012

Submitter Information:

Submitter's Name:	Stephanie Baker, BS, MBA Regulatory Affairs Project Manager
Address:	Davol Inc., Subsidiary of C. R. Bard, Inc. 100 Crossings Boulevard Warwick, RI 02886
Telephone:	(401) 825-8588
Fax:	(401) 825-8765

Device Name:

Trade Name:	Ventrio™ Light Hernia Patch with TRM Antimicrobial Coating
Common/Usual Name:	Surgical Mesh Polymeric Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric Antimicrobial Agent
Classification Code:	Class II, § 878.3300, Product Code FTL

Predicate Device Names:

- Bard Ventrio Hernia Patch, K081777 (Davol Inc.), FDA cleared on September 29,2008; K100229 – Special (Davol Inc.), FDA cleared on April 21,2010
- Pivit AB Antimicrobial Mesh, K053656 (TyRx Pharma, Inc.), FDA cleared on July 14, 2006
- Pivit AB-ST Antimicrobial Mesh, K093524 (TyRx Pharma, Inc), FDA cleared on March 26,2010

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Device Description:

The proposed Ventrio Light Hernia Patch with TRM Antimicrobial Coating is a self-expanding, nonabsorbable, sterile prosthesis. It contains two primary layers of monofilament polypropylene mesh to form a positioning pocket. This pocket is stitched with a polytetrafluroethylene (PTFE) monofilament thread to an expanded polyfluoroethylene (ePTFE) sheet. The two primary layers of polypropylene mesh are constructed of a lighter weight, "larger-pore" (as defined below), knitted polypropylene monofilament approximately 0.0043" in diameter. The polypropylene mesh used in the proposed device weighs approximately 51% less per unit area than the polypropylene mesh used in the posterior layer of the predicate Ventrio Hernia Patch (0.024 g/in^2 versus 0.049 g/in^2). The pore size of the mesh used in the proposed product is 0.082 in^2 as compared to 0.019 in^2 for the mesh used in the posterior layer of the predicate Ventrio Hernia Patch. The device contains SorbaFlex™ Memory Technology, which provides memory and stability to the device, facilitating ease of initial insertion, proper placement, and fixation. The SorbaFlex Memory Technology is comprised of an extruded polydioxanone (PDO) monofilament that is contained within a knitted polypropylene mesh sleeve. The PDO monofilament is dyed violet with D&C Violet No. 2 and fully degrades in vivo by means of hydrolysis with absorption essentially complete in 6-8 months.

The proposed Ventrio Light Hernia Patch surfaces are coated with TRM Antimicrobial Coating, which is comprised of a bioresorbable L-tyrosine succinate polymer (T) and antimicrobial agents rifampin (R) and minocycline (M). The coating is shaded orange in color due to the color of the antimicrobial agents. The TRM Antimicrobial Coating has been shown to reduce or inhibit microbial colonization on the device during the initial healing process for up to 7 days following surgery. The bioresorbable L-Tyrosine succinate polymer is essentially absorbed in 6 - 8 months based on *in vitro* studies.

The fascial side of the Ventrio Light Hernia Patch (polypropylene) allows a prompt fibroblastic response through the interstices of the mesh, allowing for tissue in-growth into the device. The visceral side of the device (ePTFE) has a submicronic porosity to minimize tissue attachment to the device.

Intended Use:

The Ventrio Light Hernia Patch is indicated for use in the reconstruction of soft tissue in procedures involving soft tissue repair where weakness exists, such as for the repair of hernias. The TRM Antimicrobial Coating has been shown to reduce or inhibit microbial colonization on the device.

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

The proposed Ventrio Light Hernia Patch with TRM Antimicrobial Coating is similar in intended use and in technological characteristics and performance when compared to the predicate devices Ventrio Hernia Patch, Pivit AB and Pivit AB-ST. All devices are intended for use in the reconstruction and repair of soft tissue deficiencies where weakness exists such as hernia repair. In addition, all devices are similar in technological characteristics with regard to materials, design, sterilization, packaging and labeling. Where minor technological differences exist between the proposed device and the predicate devices, performance testing demonstrates that these differences do not adversely affect the safety and effectiveness of the proposed device.

The proposed device, Ventrio Light Hernia Patch with TRM Antimicrobial Coating and the predicate devices Ventrio Hernia Patch, Pivit AB and Pivit AB-ST are all composed of knitted polypropylene monofilament mesh. Both the proposed device and the predicate device, Ventrio Hernia Patch, contain two primary layers of monofilament polypropylene mesh to form a positioning pocket stitched with PTFE monofilament to an ePTFE sheet. The proposed device has the same mesh configuration as the predicate, Ventrio Hernia Patch, except for four modifications, three of which are considered minor modifications.

The first minor modification involves the polypropylene monofilament mesh layer of the device. The proposed device is constructed of two primary layers of lighter weight, larger pore knitted polypropylene monofilament while the predicate Ventrio Hernia Patch contains only one layer of lighter weight, larger pore knitted polypropylene monofilament.

The second minor modification involves the polypropylene mesh surrounding the PDO monofilament recoil ring. In both the proposed and predicate devices, the PDO monofilament recoil ring is contained within polypropylene mesh. However, in the predicate device (small circle, large circle, small oval, medium oval and large oval sizes only) the PDO monofilament is contained by two layers of knitted mesh stitched with PTFE monofilament thread while in the proposed device the PDO monofilament is contained within a knitted polypropylene mesh sleeve. This sleeve is also used to contain the PDO monofilament in the extra large sizes of the predicate device.

The last minor modification involves the sizes of the devices. The predicate Ventrio Hernia Patch is marketed in 9 sizes, while the proposed device will be marketed in 5 sizes only (small circle, large circle, small oval, medium oval and large oval). In addition to the three minor modifications described above, one other modification includes the addition of the TRM antimicrobial coating containing the antimicrobial agents rifampin and minocycline to the proposed device as discussed below. Both the proposed device and the

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predicate Ventrio Hernia Patch are packaged in the same materials, Tyvek and foil, and undergo ethylene oxide (EtO) sterilization.

The proposed and predicate devices Pivit AB and Pivit AB-ST are composed of knitted polypropylene mesh. The predicate devices Pivit AB and Pivit AB-ST are composed a single layer of knitted polypropylene mesh while the proposed device contains two primary layers of knitted polypropylene mesh stitched to an ePTFE sheet with PTFE monofilament thread. In addition, the proposed device contains an absorbable PDO recoil ring while the predicate devices Pivit AB and Pivit AB-ST do not contain any recoil mechanism. Both the proposed and predicate devices are coated with a bioresorbable L-tyrosine succinate polymer coating containing the antimicrobial agents rifampin and minocycline. The proposed device has the antimicrobial agents rifampin and minocycline (minocycline hydrochloride) in equal concentrations of approximately 115 $\mu g/cm^2$ while the predicate devices Pivit AB and Pivit AB-ST have the antimicrobial agents in equal concentrations of 86.11 $\mu g/cm^2$. Both the proposed device and the predicate devices Pivit AB and Pivit AB-ST are packaged in the same materials, Tyvek and foil. The predicate devices Pivit AB and Pivit AB-ST are gamma sterilized while the proposed device is sterilized with EtO.

Performance Data:

Biocompatibility testing in accordance to the ISO 10993 series was conducted on the proposed finished device and the results indicate that the device is biocompatible per these standards.

Laboratory bench testing was performed to compare both physical and functional characteristics of the proposed device to those of the predicate device Ventrio Hernia Patch. In addition, an *in vivo* porcine study was performed to evaluate peritoneal tissue attachment, mesh contracture, mechanical tissue in-growth, and host inflammatory response associated with the proposed device at 4 weeks post-implantation. Two *in vivo* dorsal rabbit infection model studies were also performed to determine the amount of microbial colonization and macroscopic abscess formation associated with the proposed device after implantation and direct inoculation with bacteria. Analytical and *in vitro* testing was also performed on the proposed and predicate devices and include speed to kill, kinetic drug release (KDR), drug content and impurity, and polymer degradation testing.

Conclusion:

Results of the testing performed in support of this submission demonstrate that the Ventrio Light Hernia Patch with TRM Antimicrobial Coating is substantially equivalent to currently marketed predicate devices, Ventrio Hernia Patch, Pivit AB and Pivit AB-ST and is safe and effective for its intended use. In addition, the results of the testing show

that the components in the proposed device, specifically ePTFE and PDO, have no interaction with the TRM antimicrobial coating and do not affect the release profile of the antimicrobial agents rifampin and minocycline.

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

C.R. BARD, Incorporated
% Ms. Stephanie Baker, BS, MBA
Regulatory Affairs Project Manager
100 Crossings Boulevard
Warwick, Rhode Island 02886

JUL 20 2012

Re: K113229
Trade/Device Name: Ventrio™ Light Hernia Patch with TRM Antimicrobial Coating
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: July 18, 2012
Received: July 19, 2012

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

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INDICATION FOR USE STATEMENT

510(k) Number (if known): To be determined

Device Name: Ventrio™ Light Hernia Patch with TRM Antimicrobial Coating

The Ventrio™ Light Hernia Patch is indicated for use in the reconstruction of soft tissue in procedures involving soft tissue repair where weakness exists, such as for the repair of hernias. TRM Antimicrobial Coating has been shown to reduce or inhibit microbial colonization on the device.

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

510(k) Number K113225

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)