7. 510(k) Summary of Safety and Effectiveness:

OCT 23 2006

A. Submitter Information:

Submitter's Name:	Davol, Inc.
Address:	Subsidiary of C. R. **Bard**, Inc. 100 Sockanossett Crossroad Cranston, RI 02920
Telephone:	(401) 215-2642
Fax:	(401) 215-2031
Contact Person:	Gail Dow

B. Device Name:

Trade Name:	**Bard** Composix® L/P Mesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh, Polymeric

C. Predicate Device Names:

- **Bard** Large Pore *Soft*™ Mesh Pre-Shaped, K052155 (Davol Inc.), FDA cleared on 10/20/2005;
- **Bard** Composix® E/X Mesh, K002684 (Davol Inc.), FDA cleared on 10/11/2000;
- **Davol** Delivery System (currently marketed as PrecisionPass Laparoscopic Delivery Device), K041641 (Davol Inc.), FDA cleared on 07/01/2004.

D. Device Description:

The **Composix® L/P** Mesh, will consist of a layer of polypropylene mesh and a layer of expanded polytetrafloroethylene (ePTFE) stitched together using Polytetrafluroethylene (PTFE) monofilament thread sewn in a lock stitch formation. The polypropylene layer is knitted from 0.0048 inch polypropylene monofilament, which is identical to the currently marketed Large Pore *Soft*™ Mesh. The thickness of the ePTFE layer is identical to the currently marketed Composix® E/X Mesh. As with the currently marketed **Composix** E/X, the peripheral edge of the polypropylene mesh will be heat sealed to the ePTFE layer.

The layers of the **Composix** L/P Mesh will be sewn together using rows of interspaced stitching, which will allow the surgeon to tailor the product. Using the stitch pattern as a guide, the surgeon can tailor the product. For user convenience to facilitate the

deployment of the larger sized **Composix** L/P products, the larger sizes of the **Composix** L/P products will be packaged with an Introducer Tool. This Introducer Tool is similar to the rolling tines/plunger assembly and T-handle of the PrecisionPass™ Delivery Device. The Introducer Tool consists of a handle with a thin stainless steel rod. The stainless steel rod is split into two pieces along its length and has ridges around the perimeter to facilitate use. Similar to the T-handle provided with the **PrecisionPass** Device, the Introducer Tool's T-cap will be used to secure the open end of the metal rolling tines during the rolling process, then removed prior to delivering the device through the trocar.

E. Intended Use:

Bard Composix® L/P Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

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

Bard Composix® L/P Mesh and the Predicate mesh have the same indication: reinforce soft tissue, i.e., repair of hernias and chest wall defects.

The Proposed Product has similar physical attributes, performance characteristics, and materials as the Predicates **Bard** Composix® E/X and **Bard** Large Pore *Soft*™ Mesh. Furthermore, it has similar manufacturing methods as the Predicate **Bard** Large Pore *Soft*™ Mesh and Predicate **Bard** Composix E/X Mesh.

The key differences in the Proposed Product as compared to the Predicate Products, is that the Predicate **Bard** Large Pore *Soft*™ Mesh Product is a large pore single-layer polypropylene monofilament mesh and the Proposed Product is a bilayer construction. While both the Predicate **Bard** Composix E/X Mesh and the Proposed Product **Bard** Composix® L/P Mesh are similar in their bilayer construction, the two products combine different types of knitted polypropylene mesh with the same ePTFE layer. The Predicate **Bard** Composix E/X Mesh utilizes 0.006" **Bard** Flat Mesh with ePTFE, and the Proposed Product **Bard** Composix® L/P Mesh uses the 0.0048" Predicate **Bard** Large Pore *Soft*™ Mesh with a layer of ePTFE. In addition, the larger sizes of the Proposed Product **Bard** Composix® L/P Mesh will be packaged with an Introducer Tool. The **Bard** Composix® L/P Mesh Introducer Tool will facilitate rolling the device with a consistent technique; this will allow a low-profile device to be placed through the appropriate trocar sizes. The mesh side is visually distinguishable from the ePTFE side to determine correct prosthetic orientation. This is standard practice, similar to the other Composix® line products. Furthermore, the Introducer Tool is similar to the tines packaged with the Precision Pass

tool. The Precision Pass tool is packaged separately but often used jointly with the **Bard** Composix® E/X. The mode of operation, physical attributes, performance characteristics and materials of the **Bard** Composix® L/P Mesh Introducer Tool packaged with the larger sizes of the are all similar to the **Davol** Delivery System (Precision Pass tool).

G. Performance Data

Biocompatibility and bench testing provided in this submission support the safety and effectiveness of **Bard** Composix® L/P Mesh for its intended use. The biocompatibility testing completed on the product manufactured with the same materials and similar processes as the **Bard** Composix L/P Mesh demonstrate the device is non-toxic and non-sensitizing to biological tissues consistent with its intended use. Laboratory testing discussed in this submission demonstrate that the material chosen and the design utilized in manufacturing **Bard** Composix® L/P Mesh is substantially equivalent to the referenced Predicate Products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Davol Inc.
% Ms. Gail Dow
Regulatory Associate
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

OCT 23 2006

Re: K061754
Trade/Device Name: Bard® Composix® L/P Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 3, 2006
Received: October 5, 2006

Dear Ms. Dow:

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

K061754

Indications for Use

510(k) Number (if known): Unknown

Device Name: Bard® Composix® L/P Mesh

Indications for Use:

Bard Composix L/P Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

Prescription Use ✓ 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)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)