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7.0 510(k) Summary of Safety and Effectiveness:

OCT 20 2005

A. Submitter Information:

Submitter's Name:	Davol, Inc.
Address:	Subsidiary of C. R. Bard, Inc. 100 Sockanossett Crossroad Cranston, RI 02920
Telephone:	401-463-7000, Ext. 2386
Fax:	401-463-3845
Contact Person:	Lucinda L. Fox

B. Device Name:

Trade Name:	Bard® Large Pore *Soft* Mesh and *Soft* Mesh Pre-shaped
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh, Polymeric

C. Predicate Device Names:

Trade Name:	Bard Mesh (Davol Inc.)
Trade Name:	Ethicon Mersilene Polyester Fiber Mesh (Ethicon, Inc.)
Trade Name:	Ethicon Prolene Soft Polypropylene Mesh (Ethicon, Inc.)

D. Device Description:

The proposed **Bard** Large Pore *Soft* Mesh product is a single layer of mesh constructed from polypropylene monofilament with a diameter of approximately 0.048 inches. The mesh is knitted to form a strong, porous, support material. The small diameter of the polypropylene monofilament allows for a thin profile and creates a mesh with increased flexibility and a reduced amount of material compared to traditional monofilament polypropylene meshes. It is manufactured utilizing a strong knit design that allows for bi-directional flexibility and tailoring in any direction and will be marketed as a sterile, single use device available in several sizes of rectangular sheets and pre-shaped forms. Predicates **Bard** Mesh, Mersilene Mesh, and Prolene Soft are sterile, single use products that can be tailored as well.

E. Intended Use:

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Bard® Large Pore *Soft* Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. **Bard** Large Pore *Soft* Mesh Pre-Shaped is indicated for the repair of inguinal hernia defects.

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

Bard *Soft* Mesh product and the Predicate **Bard** Mesh have the same indication: reinforce soft tissue, i.e., repair of hernias and chest wall defects.

The Proposed Product has similar physical attributes and performance characteristics as the Predicates **Bard** Mesh, Mersilene Mesh, and Prolene Soft Mesh. Furthermore, it has the same materials and similar manufacturing methods as the Predicate **Bard** Mesh.

The key differences in the Proposed Product compared to the Predicate Products are the diameter of the polypropylene monofilament and the knit pattern of the mesh. In order to create a thinner, lighter weight mesh and reduce the amount of material used in the mesh compared to traditional monofilament polypropylene meshes, the Proposed Product is constructed from monofilaments with a diameter of approximately 0.048 inches. However, the weights (grams/square inch) of both Predicates Prolene Soft (0.0287) and Mersilene Mesh (0.0274) are comparable to the Soft Mesh (0.0282).

G. Performance Data

Biocompatibility and bench testing have been completed and support the safety and effectiveness of **Bard** Large Pore *Soft* Mesh for its intended use. The biocompatibility test results show that the material used in the design and manufacture of the device is non-toxic and non-sensitizing to biological tissues consistent with its intended use. Laboratory test results demonstrate that the material chosen and the design utilized in manufacturing **Bard** Large Pore Soft Mesh will meet the established specifications necessary for consistent performance during its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Ms. Lucinda L. Fox
Manager, International
Regulatory & Clinical Affairs
Davol Inc.
Subsidiary of C.R. Bard, Inc.
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K052155
Trade/Device Name: Bard® Large Pore Soft Mesh and Soft Mesh Pre-shaped
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 4, 2005
Received: August 8, 2005

Dear Ms. Fox:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K052155

Indications for Use

510(k) Number (if known): Unknown

Device Name: Bard® Large Pore *Soft* Mesh and *Soft* Mesh Pre-shaped

Indications for Use:

Bard® Large Pore *Soft* Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. **Bard** Large Pore *Soft* Mesh Pre-shaped is indicated for the repair of inguinal hernia defects.

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)

Catherine Quilliam

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

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