MAR - 1 2004

SECTION VII.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR BARD SOFT MESH

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. 2263
Fax:	401-463-3845
Contact Person:	Suzanne LaScalza
Date of Preparation:	December 5, 2003

B. Device Name

Trade name:	Bard Soft Mesh
Common/Usual name:	Surgical Mesh
Classification name:	Surgical Mesh, Polymeric

C. Predicate Device Names

Trade name: Bard Mesh (Davol Inc.)

Trade name: Atrium ProLite Ultra Mesh (Atrium Medical Corporation)

Trade name: Ethicon Mersilene Polyester Fiber Mesh (Ethicon, Inc.)

D. Device Description

The proposed Bard Soft Mesh is a single layer of mesh constructed from polypropylene monofilament with a diameter of approximately 0.004 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. The proposed device is manufactured utilizing a strong knit design that allows for bi-directional flexibility and tailoring in any direction. The proposed device will be marketed as a sterile, single use device and will be available in several sizes of rectangular sheets and pre-shaped forms. The option to resterilize unused mesh has been provided in the instructions for use.

E. Intended Use

The proposed device is indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.

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

Bard Soft Mesh and the predicate Bard Mesh have an identical intended use. Both devices are indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.

The proposed device has similar physical attributes and performance characteristics as the predicates Bard Mesh, ProLite Ultra and Mersilene Mesh. Furthermore, it has the same materials and similar manufacturing methods as the predicate Bard Mesh.

The key differences in the proposed device compared to the predicate devices is in the diameter of the polypropylene monofilaments and the knit pattern of the mesh. In order to create a thinner, lighter weight mesh while also reducing the amount of material used in the mesh compared to traditional monofilament polypropylene meshes, the proposed device was constructed from monofilaments with a diameter of approximately 0.004 inches similar to the predicate ProLite Ultra. The knit pattern of the mesh was designed in order to create a mesh with a soft feel and to allow for a more even stretch in both directions of the prosthesis.

G. Performance Data

Biocompatibility and bench testing have been completed and support the safety and effectiveness of Bard 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 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

MAR - 1 2004

Ms. Suzanne LaScalza
Regulatory Affairs Associate
Davol, Inc.
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K033814
Trade/Device Name: Bard Soft Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh polymeric
Regulatory Class: II
Product Code: FTL
Dated: December 5, 2003
Received: December 9, 2003

Dear Ms. LaScalza:

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 (301) 594-4659. 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,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033814

Device Name: Bard Soft Mesh

Indications for Use: Indicated to reinforce soft tissue where weakness exists, i.e., repair of hernias and chest wall defects.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BLEOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, I[illegible]orative
and Neurological De[illegible]s

510(k) Number K033814