K024008

FEB 2 0 2003

SECTION 6.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE VENTRALEX PATCH

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:	Brian A. Kanerviko
Date of Preparation:	December 3, 2002

B. Device Name

Small Bard Ventralex Patch

C. Predicate Device Name

Trade name: Bard Ventralex Hernia Patch (K021736)

D. Device Description

The proposed Ventralex Patch is a self-expanding, three layer device. Two layers consist of polypropylene mesh. The top layer of polypropylene mesh forms a positioning strap and pocket. The purpose of the strap and pocket is to facilitate placement, positioning and fixation of the device. After the device has been properly placed and attached, the positioning strap must be removed and properly discarded. The monofilament PET polymer "ring" is captured between the two layers of polypropylene mesh and adds stability to the device enabling greater simplicity and assurance in the proper placement. The third layer of the device is a single layer of expanded polytetrafluoroethylene (ePTFE) that is attached to the polypropylene mesh with an interlocking PTFE stitch pattern. The peripheral edge of the polypropylene mesh is heat sealed to the ePTFE layer.

E. Intended Use

The Bard Ventralex Hernia Patch is intended for use in all forms of hernia repair requiring reinforcement with a nonabsorbable support material. The small Bard Ventralex Patch is also intended to repair soft tissue deficiencies, including deficiencies caused by trocars.

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

The small Ventralex Patch has same technological and performance characteristics as the predicate Ventralex Patch.

The predicate Ventralex Patch is intended for use in all forms of hernia repair requiring reinforcement with nonabsorbable support material.

The Bard Ventralex Hernia Patch is intended for use in all forms of hernia repair requiring reinforcement with a nonabsorbable support material. The small Bard Ventralex Patch is also intended to repair soft tissue deficiencies caused by trocars.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

C. R. Bard, Inc.
c/o Davol, Inc.
Brian A. Kanerviko
Regulatory and Clinical Affairs Associate
100 Sockanossett Crossroad
P. O. Box 8500
Cranston, Rhode Island 02920

Re: K024008
Trade/Device Name: Small Bard Ventralex Patch
Regulation Number: 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 3, 2002
Received: December 4, 2002

Dear Mr.Kanerviko:

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). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost

for 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

K024008

510(k) Number (if known): _____

Device Name: Ventralex Patch

Indications for Use: The Bard Ventralex Hernia Patch is intended for use in all forms of hernia repair requiring reinforcement with a nonabsorbable support material. The small Bard Ventralex Patch (REF 0010301) is also intended to repair soft tissue deficiencies including deficiencies caused by trocars.

(Please do not write below this line – Continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024008