AUG 2 3 2002

K022350

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE BARD CRURASOFT 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. 2642
Fax:	401-463-3845
Contact Person:	Brian A. Kanerviko
Date of Preparation:	July 18, 2002

B. Device Name

Bard CruraSoft Patch

C. Predicate Device Name

Trade name: Bard Composix E/X mesh, PTFE mesh, Gore SEAMGUARD Staple Line Reinforcement Material

D. Device Description

The proposed device is heart shaped and has a porous polytetrafluoroethylene (PTFE) side and an expanded polytetrafluoroethylene (ePTFE) side that are connected to each other on the edge with an interlocking monofilament PTFE stitch. There is also a row of stitching that is in a "V" shape which allows the device to be tailored. The prosthesis may be trimmed to the outside of the "V" stitching. The "V" stitching will continue to keep the two layers of the device together if it is tailored. An ePTFE flap is sewn to the superior edge of the patch to minimize the possibility of the device adhering to undesired structures, such as the esophagus. The proposed device is preshaped and presized to offer maximum ready-to-use benefits.

E. Intended Use

The Bard CruraSoft Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of chest wall defects and hernias, including diaphragmatic/hiatal hernias.

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

The proposed and predicate devices are similar in that all three devices are surgical implants. One of the predicates is comprised entirely of PTFE, while the other is a combination of polypropylene and ePTFE. The proposed product is taking the existing PTFE from the predicate pre-amendment device and attaching it to the same ePTFE as used in predicate Composix E/X. The PTFE monofilament thread used to attach the ePTFE to PTFE is the same as the thread used in predicate Composix E/X.

The difference between the proposed and predicate devices includes the shape and the attachment of PTFE to ePTFE. The proposed device is heart shaped with ePTFE on one side and PTFE on the other. An ePTFE flap is sewn to the superior edge of the PTFE side of the device with an interlocking monofilament PTFE stitch. The ePTFE runs slightly over the top corners of the PTFE side of the device. The device is sewn together using an interlocking monofilament PTFE stitch.

The Gore SEAMGUARD Staple Line Reinforcement Material (K001789) indication includes the repair of hernias, including diaphragmatic hernias. This indication is the same as the proposed device indication statement.

The proposed device is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of chest wall defects and hernias, including diaphragmatic/hiatal hernias. The predicate Composix E/X and the proposed device are both intended for use to reinforce soft tissues where weakness exists. Both devices give examples of chest wall defects and hernias.

The predicate PTFE mesh is indicated for use primarily in the repair of hernias and defects resulting from the surgical wounds of extensive cancer resections. The proposed device indication for use does not include the repair of defects strictly caused from surgical wounds of extensive cancer resections. Instead, it focuses on the repair of hernias and defects. The proposed device and predicate PTFE mesh share this in their indication for use.

G. Performance Data

Bench testing has been completed and supports the safety and effectiveness of the Bard CruraSoft Patch for its intended use.

Laboratory test results demonstrate that the materials chosen and the design utilized in manufacturing the Bard CruraSoft Patch will meet the established specifications necessary for consistent performance during their intended use and support substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2002

Brian A. Kanerviko
Regulatory and Clinical Affairs Associate
Davol, Inc.
100 Sockanossett Crossroad
P. O. Box 8500
Cranston, Rhode Island 02920

Re: K022350
Trade/Device Name: Bard Crurasoft Patch
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: July 11, 2002
Received: July 19, 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

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

510(k) Number (if known): K02 2350

Device Name: **Bard CruraSoft Patch**

Indications for Use: The Bard CruraSoft Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of chest wall defects and hernias, including diaphragmatic/hiatal hernias.

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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)

for Mark N. Milhern *(Optional Format 1-2-96)*

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

510(k) Number K02350