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SECTION VII.

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE BARD® CK™
PARASTOMAL 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. 2529
Fax: 401-463-3845
Contact Person: Karen S. Gwozdowski Gauvin
Date of Preparation: July 27, 2004

B. Device Name

Trade Name: Bard CK Parastomal Hernia Patch
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh, Polymeric

C. Predicate Device Name

Trade name: Bard® Composix® Kugel® Mesh (Davol Inc.)
Trade name: Gore® SEAMGUARD Staple Line Reinforcement Material
(W.L. Gore & Associates, Inc.)

D. Device Description

The proposed device is a self-expanding, two-layered polypropylene mesh containing an extruded monofilament PET polymer "ring". The top layer of polypropylene mesh has two slits in it to form pockets. The purpose of the pockets is to facilitate placement, positioning and fixation of the device. The mesh is constructed from knitted polypropylene monofilament. The monofilament PET "ring" adds stability to the device facilitating placement and assurance in the proper placement of the patch. A single layer of expanded polytetrafluoroethylene (ePTFE) is attached to the polypropylene mesh. The attachment is accomplished with an interlocking stitch using polytetrafluoroethylene (PTFE) monofilament. The peripheral edge (excluding the off-center opening) of the polypropylene mesh is heat sealed to the ePTFE layer. An off-center opening in the proposed device accommodates the stoma and this opening

is surrounded by an ePTFE collar. The ePTFE collar is attached to the mesh side of the proposed device with an interlocking stitch using PTFE monofilament. A slit in the proposed device extends from the opening in the proposed device to the perimeter to facilitate positioning of the proposed device around the stoma. The proposed device is preshaped and presized to offer maximum ready-to-use benefits.

E. Intended Use

The Bard CK Parastomal Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of abdominal wall defects and hernias, including parastomal hernias.

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

The proposed device has the same exact materials as the predicate Composix Kugel, along with similar physical attributes, performance characteristics and manufacturing methods as the predicate Composix Kugel.

The difference between the proposed and predicate device includes the opening in the proposed device surrounded by the ePTFE collar and the slit in the proposed device to access the opening in the proposed device. The predicate device does not have an opening surrounded by an ePTFE collar and does not have a slit in the device. The shape of the memory recoil "ring" in the proposed device is different from the shape of the memory recoil "ring" in the predicate device.

The Gore SEAMGUARD Staple Line Reinforcement Material (K001789) indication includes the repair of hernias, including paracolostomy 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 abdominal wall defects and hernias, including parastomal hernias. The predicate Composix Kugel and the proposed device are both intended for use in hernia repair. The proposed device provides an additional example of a parastomal hernia. The parastomal hernia is part of the broader indication of a hernia. A hernia is part of a broader indication of soft tissue deficiency. Therefore, the predicate Composix Kugel and the proposed device have the same indication statement.

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G. Performance Data

Biocompatibility and bench testing have been completed and support the safety and effectiveness of the Bard CK Parastomal Hernia Patch for its intended use.

The biocompatibility test results show that the material used in the design and manufacture of the device are non-toxic and non-sensitizing to biological tissues consistent with their intended use. Laboratory test results demonstrate that the materials chosen and the design utilized in manufacturing the Bard CK Parastomal Hernia Patch will meet the established specifications necessary for consistent performance during their intended use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen S. Gwozdowski Gauvin
Regulatory Affairs Associate
Davol, Inc.
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K042026
Trade/Device Name: Bard® CK™ Parastomal Hernia Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: July 27, 2004
Received: July 28, 2004

Dear Ms. Gauvin:

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.

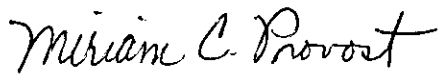
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

K042026

Indications for Use

510(k) Number (if known):

Device Name: **Bard® CK™ Parastomal Hernia Patch**

Indications for Use: The Bard CK Parastomal Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of abdominal wall defects and hernias, including parastomal hernias.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW 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, Restorative,
and Neurological Devices**

510(k) Number K042026