APR 10

K052322

SECTION 7.0

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE BARD® COLLAMEND™ IMPLANT

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. 2389
Fax:	401-463-3845
Contact Person:	Robin Drago
Date of Preparation:	August 12, 2005

B. Device Name

Trade Name:	Bard CollaMend Implant
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh

C. Predicate Device Name

Trade name: Permacol® Implant (Tissue Science Laboratories, PLC.)

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

Trade name: FortaGen® Porcine Collagen Surgical Implant (Organogenesis, Inc.)

D. Device Description

The proposed device is a sterile, solid, sheet of lyophilized, acellular porcine dermal collagen and its constituent elastin fibers. It is processed to remove all non-collagenous cellular components and is cross-linked to increase strength and endurance. The proposed device allows cellular infiltration and replacement by host tissue, forming a strong repair of soft tissue defects. The proposed device will be made available in various sizes and shapes, ranging from a 4" x 6" ellipse to a 10" x 14" rectangle. The thickness of the devices will be approximately 1mm. Surgeons will need to rehydrate the product before implanting it into the patient. The proposed device will be marketed as a sterile, single use device.

E. Intended Use

The Bard CollaMend Implant is indicated to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.

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

The proposed device and the three predicate devices are all generally intended for use in the repair of soft tissue deficiencies, including hernias.

The proposed device is similar to the three predicate devices in principle of operation and general design. The key differences in the proposed device to the predicate devices are in the details of the device design.

Both the proposed device and the predicate Permacol Implant are manufactured from acellular porcine dermal collagen and its constituent elastin fibers. The predicate FortaGen Implant is manufactured from layers of purified porcine intestine, and the predicate Mersilene Mesh is manufactured from multifilament polyester.

The manufacturing processes for the proposed device, predicate Permacol Implant and FortaGen Implant are unique, but each of these processes contains decontamination/viral inactivation, cross-linking of the material, and sterilization of the device.

The proposed device must be completely hydrated before use by immersion in sterile saline solution or sterile lactated ringers solution for 3-5 minutes. The predicate Permacol Implant and FortaGen Implants are packaged moist for sterilization. The predicate Permacol Implant requires that the user rinse the implant before implantation in a patient, whereas the predicate FortaGen Implant does not require rinsing or rehydration of the implant unless the implant becomes dehydrated before implantation in a patient.

G. Performance Data

Biocompatibility testing will be completed and passed before the Bard CollaMend Implant is released. These biocompatibility test results will show that the material used in the design and manufacture of the proposed device is non-toxic and non-sensitizing to biological tissues consistent with its intended use.

An animal implant study was performed to confirm the functionality and in-growth characteristics of the Bard CollaMend Implant as compared to the predicate Permacol Implant.

Laboratory test results demonstrate that the material chosen, the manufacturing process, and the design utilized for the Bard CollaMend Implant 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

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Davol Inc.
Subsidary of C.R. Bard, Inc.
c/o Ms. Robin Drago
VP of Regulatory and Clinical Affairs
100 Sockanossett Crossroad
P.O. Box 8500
Cranston, Rhode Island 02920

Re: K052322
Trade/Device Name: Bard® CollaMend™ Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: March 27, 2006
Received: March 28, 2006

Dear Ms. Drago:

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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052322

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Indications for Use

510(k) Number (if known):

Device Name: **Bard® CollaMend™ Implant**

Indications for Use: The Bard CollaMend Implant is indicated to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.

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)

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

510(k) Number K052322