Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Sockanossett Crossroad
P.O. Box 8500
Cranston, RI 02920
401 463-7000

K971745

DAVOL

Bard® Composite Prosthesis

AUG - 6 1997

Section VII

510(k) Summary of Safety and Effectiveness Information

A. Submitter Information

Submitter's Name:	Jeannette G. Cloutier
Address	Davol Inc. 100 Sockanossett Crossroad Cranston, RI 02920
Telephone No.	401-463-7000, Ext. 2728
Fax No.	401-463-3845
Contact Person:	Jeannette G. Cloutier
Date of Preparation:	May 9, 1997

B. Device Name

Trade Name:	**Bard** Composite Prosthesis
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh, Polymeric

C. Predicate Devices Name

Trade Name:	**Bard Marlex** Mesh (Davol Inc.) GORE-TEX Dual Mesh (W. L. Gore & Associates, Inc.)

D. Device Description

The proposed **Composite Mesh** is manufactured from knitted polypropylene monofilament with a diameter of 6 mil. The unique knitting process for the **Composite Mesh** produces a flat double layer of mesh. This double layer of mesh is knitted and interconnected simultaneously during the knitting process. One side of one layer of mesh is heat bonded to a single layer of expanded polytetrafluoroethylene (e-PTFE).

BARD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jeannette G. Cloutier
Sr. Regulatory Affairs Administrator
Davol, Inc.
100 Sockanossett Crossroad
PO Box 8500
Cranston, Rhode Island 02920

AUG - 6 1997

Re: K971745
Trade Name: Bard® Composite Prosthesis
Regulatory Class: II
Product Code: FTL
Dated: May 9, 1997
Received: May 12, 1997

Dear Ms. Cloutier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

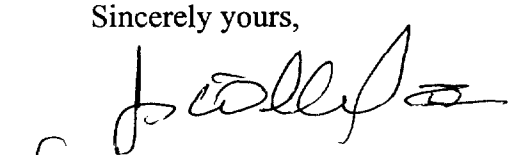
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

K971745

Section I - D

510(K) Number: K971745

Device Name: BARD® COMPOSITE PROSTHESIS

Indications for Use: Reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Or

Over-The-Counter Use____

(Optional Format 1-2-96)

E. Intended Use of the Device

The **Composite Mesh** is intended for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

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

The 510(k) Substantial Equivalence Decision-Making Process (Detailed) decision tree (ODE guidance memo #K86-3) was utilized to make a determination of substantial equivalence. The answers to the following questions from this decision tree lead to a determination of substantial equivalence.

1. Does New Device Have Same Indication Statements?

Yes. The proposed **Composite Mesh** and the Predicate GORE-TEX have identical intended use. Both devices are intended for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernia and chest wall defects.

The proposed **Composite Mesh** and the Predicate Marlex have similar intended use. The Predicate Marlex is indicated for use to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects.

2. Does New Device Have the Same Technological Characteristics, e.g., Design, Materials, etc.?

No. The proposed **Composite Mesh** and the predicate devices are similar in that the devices are provided sterile, single use for the repair of hernias and chest wall defects. The proposed **Composite Mesh** and the Predicate GORE-TEX are manufactured to provide one side containing large pores for tissue ingrowth and an opposite side with small pores to limit ingrowth. The e-PTFE side of the **Composite Mesh** and the smooth side of Predicate GORE-TEX have similar surface morphology. Additionally, the proposed **Composite Mesh** is manufactured from knitted polypropylene monofilament with a diameter of approximately 6 mil, which is identical to the material used to knit the currently marketed Predicate Marlex. Also, the knit structure of the proposed **Composite Mesh** is similar to the knit structure of the Predicate Marlex.

However, the entire construction of the **Composite Mesh** includes two layers of polypropylene mesh and one layer of e-PTFE, while the Predicate GORE-TEX is manufactured from two layers of e-PTFE and the Predicate Marlex is manufactured from one layer of polypropylene mesh.

3. Could the New Characteristics Affect Safety or Effectiveness?

Yes. The single layer of e-PTFE bonded to a double layer of polypropylene which comprises

the **Composite Mesh** as compared to the two layers of e-PTFE for the Predicate GORE-TEX and the one layer of polypropylene for the Predicate Marlex could affect both safety and effectiveness.

4. **Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**

No. Surgical meshes, such as the proposed **Composite Mesh** and the predicate devices, are generally intended for use in the reconstruction of soft tissue deficiencies. The safety and effectiveness questions are not new and include questions such as pore size, surface roughness, mesh strength, biocompatibility, and suture retention. Additionally, there are a variety of other meshes currently on the market with different characteristics compared to the proposed **Composite Mesh** or the predicate devices.

5. **Do Accepted Scientific Methods Exist for Assessing Effects of the new Characteristics?**

Yes. The assessment of the effects of the characteristics of the proposed **Composite Mesh** can be determined by performing common measures utilized for surgical implant fabrics in the industry. The assessments to characterize the effects include pore size, surface roughness, suture retention strength, burst strength and in-vivo testing.

6. **Are Performance Data Available to Assess Effects of New Characteristics?**

Yes. Laboratory testing was performed to assess the effects of the new characteristics of the proposed **Composite Mesh**. These tests compared the proposed **Composite Mesh** against the predicate devices, where applicable. These tests include:

(1) the physical characteristics in terms of pore size, surface roughness, and surface morphology (scanning electron micrographs);

(2) performance in terms of suture retention and burst strength testing were performed;

(3) the chemical characteristics of the e-PTFE of both the proposed **Composite Mesh** and the Predicate GORE-TEX by testing utilizing the Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC); and,

(4) in-vivo testing for a quantitative measure of organ adhesion characteristics of the e-PTFE layer, a qualitative assessment of tissue ingrowth characteristics, and overall performance in a simulated clinical situation.

In addition, biocompatibility testing, performed in accordance with ODE memorandum #G95-1 (International Standard ISO-10993, Part 1), has been conducted on the proposed **Composite Mesh**.

7. **Does Performance Data Demonstrate Equivalence?**

Yes. Based on the results of the laboratory testing provided in Section VI of this submission,

the physical and chemical characteristics of the proposed **Composite Mesh** are comparable to that of the currently marketed predicate devices. Additionally, the results from the in-vivo testing indicate that the adhesion response for the proposed **Composite Mesh** is comparable to the Predicate GORE-TEX and the gross tissue ingrowth is comparable to both predicate devices. Results from the biocompatibility tests have shown that the proposed **Composite Mesh** is non-toxic and non-sensitizing.

Conclusion:

Based on the FDA's decision tree, the subject device, the proposed **Composite Mesh**, is substantially equivalent to the predicate devices.

Contact Person: Jeannette G. Cloutier

Jeannette G. Cloutier
Sr. Regulatory Affairs Administrator
Dated: May 9, 1997