DAVOL INC.
SUBSIDIARY OF C.R. BARD, INC.
100 SOCKANOSSETT CROSSROAD
P.O. BOX 8500
CRANSTON, RI 02920

JUN 2 2 1999

K991637

7.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE BARD® PRESHAPE MESH WITH e-PTFE PATCH

7.1 Submitter Information

Submitter's Name:	Rini Georgekutty
Address:	Davol Inc. 100 Sockanossett Crossroad Cranston, RI 02920
Telephone No.:	401-463-7000 ext. 2642
Fax No.:	401-463-3845
Contact Person:	Rini Georgekutty
Date of Preparation:	April 12, 1999

7.2 Device Name

Trade Name:	Bard Sperma-Tex Preshaped Mesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh, Polymeric

7.3 Predicate Device Name

Trade Name:	Bard Mesh Preshape Bard Composix Mesh

7.4 Device Description

The Proposed Device, the Bard Sperma-Tex Preshaped Mesh, is manufactured from knitted polypropylene monofilament. The mesh is cut in a thumbnail design. A patch of e-PTFE is stitched onto one side of the mesh, at the rounded corner, with polypropylene monofilament.

7.5 Intended Use

The Proposed Device is indicated for the repair of inguinal hernia defects.

7.6 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 decision tree questions lead to a determination of substantial equivalence.

1. Does New Device Have Same Indication Statements?

Yes. The Proposed Device and the Predicate Preshape have identical intended use. Both devices are indicated for the repair of inguinal hernia defects.

The Proposed Device and the Predicate Composix have similar intended use. The Predicate Composix is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

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

No. The Proposed Device is a combination of the features in the Predicate Preshape and the Predicate Composix. The Proposed Device is a single layer of polypropylene mesh in a thumbnail configuration with a patch of e-PTFE sewn with polypropylene monofilament on one side of the mesh, in the medial corner.

The Proposed Device and the Predicate Preshape are similar in that both devices are provided sterile, single use for the repair of inguinal hernia defects. Also, both devices use the same polypropylene mesh and mesh design. The polypropylene mesh for both devices is manufactured from identical polypropylene monofilament and has identical mesh properties (weave, thickness etc.), configuration (thumbnail design) and dimensions. The Proposed Device is similar to the Predicate Composix in that both are surgical meshes, which exhibit the properties of e-PTFE and polypropylene. Polypropylene allows for tissue in-growth while e-PTFE with small pore size reduces tissue attachment to the mesh.

The differences between the Proposed Device and the predicate devices are that the e-PTFE is attached in a different manner and supplied by a different vendor. For the Proposed Device, the e-PTFE is attached to a single layer of polypropylene mesh using polypropylene monofilament. For the Predicate Composix, the e-PTFE is heat bonded to the inner layer of two layers of polypropylene mesh. The e-PTFE used in the Proposed Device is supplied by a different vendor but provided to the same specifications as the e-PTFE used in the Predicate Composix.

3. Could the New Characteristics Affect Safety or Effectiveness?

Yes. The patch of e-PTFE stitched onto a single layer of polypropylene may affect safety and effectiveness when compared to a single layer of polypropylene mesh alone (Predicate Preshape) or an e-PTFE layer heat bonded to a double layer of polypropylene (Predicate Composix).

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

No. Surgical meshes, such as the Proposed Device and the predicate devices are generally intended for use in reinforcing soft tissue where weakness exists. The safety and effectiveness questions raised with the Proposed Device are not new. All surgical meshes must address questions of biocompatibility, mesh strength and material properties such as pore size and surface roughness.

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

Yes. The effects of the characteristics of the Proposed Device can be assessed by performing experiments that are common in evaluating surgical mesh traits. Standardized tests are available for assessing biocompatibility of materials used in medical devices. Also, tests are available to measure the material and mechanical properties of the mesh such as pore size and burst strength.

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

Yes. Testing was performed to assess the effects of the new characteristics of the Proposed Device. The new characteristics are the following:

- Addition of a stitched e-PTFE patch to the original preshape design, on one side (compared to the Predicate Preshape).
- New e-PTFE vendor (compared to the Predicate Composix).

The effect of stitching a patch of e-PTFE onto the mesh on one side was evaluated through laboratory testing. The testing was conducted to insure that the stitching of e-PTFE onto the mesh did not compromise the strength of the polypropylene mesh. The Proposed Device was evaluated against the Predicate Preshape since they share identical intended use.

The use of a new e-PTFE vendor was assessed through evaluation of e-PTFE material properties. The material properties of the e-PTFE used in the Proposed Device and the currently marketed Predicate Composix were both analyzed to confirm that they were equivalent materials. The e-PTFE of the Proposed Device was required to exhibit the same chemical and surface properties of the e-PTFE used in the Predicate Composix since in both products the e-PTFE function is to minimize tissue attachment to the mesh.

Biocompatibility data for the Proposed Device is available in the Predicate Composix Premarket Notification. All materials used in the Proposed Device are already in use in the currently marketed Predicate Composix. The Proposed Device uses identical polypropylene material as the Predicate Composix. The e-PTFE used in the Proposed Device and the Predicate Composix are both 100% e-PTFE supplied to the same specifications. Since no new materials are introduced, biocompatibility data presented in the Predicate Composix Premarket Notification is used to support the Proposed Device. This testing was performed in accordance with FDA General Memorandum #G95-1.

7. Does Performance Data Demonstrate Equivalence?

Yes. Based on the biocompatibility test results obtained from the Predicate Composix, the materials used in the Proposed Device were shown to be non-toxic and non-sensitizing. The polypropylene and e-PTFE materials are acceptable for use in a tissue-contacting permanent implant.

Positive results were also obtained from the laboratory testing. Laboratory testing substantiated that stitching a patch of e-PTFE onto a single layer of polypropylene mesh with polypropylene monofilament did not adversely effect the mesh integrity when compared to the Predicate Preshape. The polypropylene mesh of the Proposed Device is identical to the Predicate Preshape. Material evaluations also confirmed that the e-PTFE used in the Proposed Device was similar to the e-PTFE used in the currently marketed Predicate Composix. Chemical and surface evaluations revealed similar material properties. Both materials have the pore size and surface roughness that is needed to minimize tissue attachment. References indicate that a surface pore size of less than 1 micron on average minimized cellular penetration and tissue attachment.[1,2,3] The pore size of the e-PTFE in the laboratory testing for the Proposed Device was .33 microns. In regards to surface roughness, surfaces with projections of 10-15 microns resulted in increased cellular attachment.[4] Textured surfaces with average projection heights of 12 microns resulted in increased cell adhesion.[5]

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Therefore, a surface with an average roughness of less than 10 microns would minimize cellular and tissue attachment. The Proposed Device had an average surface roughness of .12 microns in the laboratory testing. Also, the animal study conducted for the Predicate Composix provides support for tissue in-growth into the polypropylene mesh.

CONCLUSION

Based on the above information, the Proposed Device is substantially equivalent to the Predicate Preshape and the Predicate Composix.

Robin Drago 5/10/99

Robin Drago
Manager of Regulatory & Clinical Affairs,
Davol, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 1999

Ms. Rini Georgekutty
Regulatory and Clinical Affairs Administrator
Davol, Inc., Subsidiary of C.R. Bard, Inc.
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K991637
Trade Name: Sperma-Tex Preshaped Mesh
Regulatory Class: II
Product Code: FTL
Dated: May 10, 1999
Received: May 12, 1999

Dear Ms. Georgekutty:

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 requirement, 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,

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

510(k) Number (if known): K991637

Device Name: Bard® Sperma-Tex Preshaped Mesh

Indications For Use: **Repair of Inguinal Hernia 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991637