K031332/P1

MAY 15 2003

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	Terrina Wilder
Contact Person's Telephone Number:	770-784-6160
Contact Person's Fax:	770-784-6419
Date of Preparation:	April 21, 2003

B. DEVICE NAME:

Trade Name:	Bard® PelviSoft™ Acellular Collagen BioMesh
Common / Usual Name:	Surgical Mesh
Classification Name:	Polymeric Surgical Mesh (21 CFR 878.3300)

C. PREDICATE DEVICE NAME:

Trade Name: Permacol® Acellular Collagen Matrix
SurgiSIS™

D. DEVICE DESCRIPTION:

Bard® PelviSoft™ Acellular Collagen BioMesh is a sterile, off-white, moist, tough but flexible fibrous mesh of acellular porcine dermal collagen and its constituent elastin fibers. Presented moist in sterile saline, Bard® PelviSoft™ Acellular Collagen BioMesh is double vacuum-packed and heat sealed in peel-open aluminum foil (inner) and peel-open polyester/polyethylene (outer) pouches which are impermeable to oxygen and moisture.

E. INTENDED USE:

Bard® PelviSoft™ Acellular Collagen BioMesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for urethral procedures, vaginal prolapse and reconstruction of the pelvic floor.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The processing and materials of Bard® PelviSoft™ Acellular Collagen BioMesh and Permacol®, the predicate device, are the same.

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G. PERFORMANCE DATA SUMMARY:

Bard® PelviSoft™ Acellular Collagen BioMesh is substantially equivalent to the predicate devices with regard to biocompatibility (Permacol®), materials (Permacol®) and product characterization (Permacol® and SurgiSIS™). The modified design does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2003

Ms. Terrina Wilder
Senior Regulatory Affairs Specialist
C.R. Bard, Inc.
Urological Division
8195 Industrial Boulevard
Covington, Georgia 30014

Re: K031332
Trade/Device Name: Bard® PelviSoft™ Acellular Collagen BioMesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: April 25, 2003
Received: April 29, 2003

Dear Ms. Wilder:

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. 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" (21CFR Part 807.97) you may obtain. 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,

Miriam C. Provost

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

K031332

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Bard® PelviSoft™ Acellular Collagen BioMesh

Indications for Use:

Bard® PelviSoft™ Acellular Collagen BioMesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for urethral procedures, vaginal prolapse, and reconstruction of the pelvic floor.

Miriam C. Provost

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

510(k) Number K031332

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)