

**Bard Urological Division**

C.R. Bard, Inc.  
13183 Harland Drive  
Covington, GA 30014

MAR 12 2007

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**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.  
Bard Urological Division  
Address: 13183 Harland Drive  
Covington, GA 30014  
Contact Person: John C. Knorpp  
Contact Person's Telephone Number: 678-342-4920  
Contact Person's Fax: 770-788-5513

**B. DEVICE NAME:**

Trade Name(s): Avaulta™ Solo Support System  
Avaulta™ Plus Biosynthetic Support System  
Common/Usual Name: Surgical Mesh  
Classification Names: 79 FTL – Mesh, Surgical, Polymeric  
CFR Reference: 21 CFR 878.3300  
Classification Panel: General and Plastic Surgery

**C. PREDICATE DEVICE NAME:**

Trade Names: Bard CollaMend™ Implant – K052322  
UGYTEX® Dual Knit Mesh – K051503

**D. DEVICE DESCRIPTION:**

The Avaulta™ Support System includes a sterile, single use, permanent implant that provides long term reinforcement to support structures in the correction of anterior or posterior vaginal wall prolapse. The central soft knit section provides compliant organ support while the strong knit arms provide improved strength for tension free fixation of the implant.

The Avaulta™ Plus Biosynthetic Support System and Avaulta™ Solo support system both utilize a nonabsorbable monofilament, polypropylene mesh to provide long-term reinforcement for support structures. The Avaulta™ Plus Biosynthetic Support System adds a porous, acellular, ultra-thin sheet of crosslinked collagen attached to the polypropylene mesh which serves to establish a protective barrier between mucosal tissue and

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the polypropylene mesh and contains apertures uniformly sized to allow for ingrowth of host tissue and capillary vessels.

**E. INTENDED USE:**

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

**F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:**

The subject Avaulta™ Support System has the same intended use, general design and fundamental scientific technology as the predicate devices.

**G. PERFORMANCE DATA SUMMARY:**

The appropriate testing to determine substantial equivalence was completed. This includes testing in accordance with *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* (March 22, 1999).



MAR 27 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Bard Urological Division  
% Mr. John Knorpp, RAC  
Manager, Regulatory Affairs  
13183 Harland Drive  
Covington, Georgia 30014

Re: K063712

Trade/Device Name: Avaulta Solo™ Support System  
Avaulta Plus™ Biosynthetic Support System

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical mesh

Regulatory Class: II

Product Code: FTL

Dated: December 8, 2006

Received: December 14, 2007

Dear Mr. Knorpp:

This letter corrects our substantially equivalent letter of March 12, 2007.

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 (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 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.

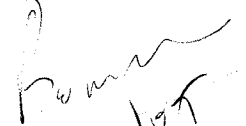
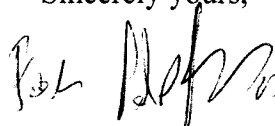
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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This letter will allow you to continue 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 (240) 276-3150 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

3/22/09

Enclosure

*K063712*

**1.3** Indications for Use Statement

510(k) Number (if known): \_\_\_\_\_

Device Name: Avaulta™ Support System

Indications for Use:

The Avaulta™ Support System is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)



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

510(k) Number   14063712  

(Recommended Format 11/13/2003)