

Bard Urological Division
C. R. Bard, Inc.
13183 Harland Dr.
Covington, GA 30014

SEP 30 2008

K063712
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BARD

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 – Mesh, Surgical, Polymeric (OTP, PAI)
CFR Reference: 21 CFR 878.3300
Classification Panel: General and Plastic Surgery

C. PREDICATE DEVICE NAME:

Trade Names: Avaulta™ Solo Support System
Avaulta™ Plus Biosynthetic Support System
K063712

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 device.

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).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

C.R. Bard, Incorporated
% John C. Knorpp, RAC
Director, Regulatory Affairs
Bard Urological Division
13183 Harland Drive
COVINGTON GA 30014

Re: K082571
Trade/Device Name: Avaulta Solo™ Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP, PAI
Dated: September 3, 2008
Received: September 5, 2008

Dear Mr. Knorpp:

This letter corrects our substantially equivalent letter of September 30, 2008.

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.

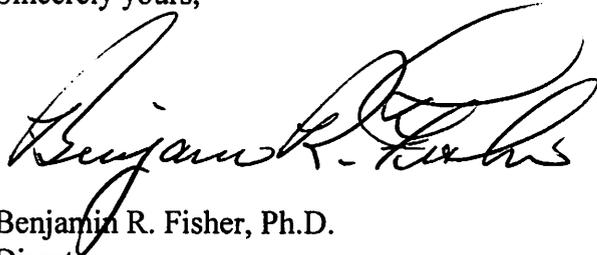
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, written over a light background.

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082571

1.4 Indications for Use Statement

510(k) Number (if known): K082571

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)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Neil R. Dyer for MRM

Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082571

(Recommended Format 11/13/2003)