K083859

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JAN 15 2009

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:	Terri Morris
Contact Person's Telephone Number:	678-342-4922
Contact Person's Fax:	770-788-5605

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 and K082571

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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

C.R. Bard, Inc.
% Mr. Terri Morris
Regulatory Affairs Specialist II
13183 Harland Drive
COVINGTON GA 30014

SEP 28 2012

Re: K083839
Trade/Device Name: Avaulta™ Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP, PAI
Dated: December 16, 2008
Received: December 23, 2008

Dear Mr. Morris:

This letter corrects our substantially equivalent letter of January 15, 2009.

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.

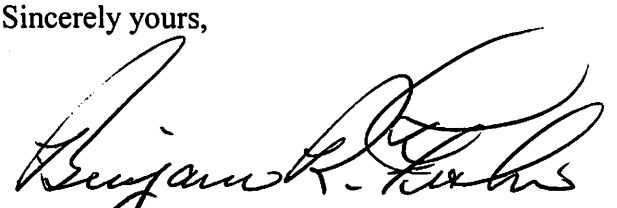
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



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

1.4 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 P Ogden for mxn

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

510(k) Number K083839

(Recommended Format 11/13/2003)