



USER: JOHNSON, SHEVON E (sxj)

FOLDER: K083839 - 62 pages (FOI:09004691)

COMPANY: C.R. BARD, INC. (CRBARD)

PRODUCT: MESH, SURGICAL, POLYMERIC (FTL)

SUMMARY: Product: AVAULTA SOLO SYNTHETIC
SUPPORT SYSTEM, AVAULTA PLUS
BIOSYNTHETIC SUPPO

DATE REQUESTED: Tue Nov 09 24:00:00 2010

DATE PRINTED: Fri Jan 14 06:04:41 2011

Note: Releasable Version

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L083839

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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 FTL – Mesh, Surgical, Polymeric
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

K083839 2/2

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
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 15 2009

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

Dear Mr. Morris:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083839

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

510(k) Number K083839

(Recommended Format 11/13/2003)

Document Cover Sheet:

K083839-K7197

FSR0701-000

Date of Submission:	16-DEC-2008
Description:	AVAULTA SOLO SYNTHETIC SUPPORT SYSTEM, AVAULTA PLUS BIOSYNTH
Date of Scan:	30-JAN-2009
Document Prep:	MH 1/30/09
Scanner:	MH 1/30/09
Image Quality Reviewer:	



Document Expected	Page # Start	Page # End	Page In Doc	Indexer
Decision Letter 15-JAN-2009	1	2	3	<input type="checkbox"/>
Indications for Use 15-JAN-2009	3	3	2	<input type="checkbox"/>
Reviewer Memorandum 14-JAN-2009	4	5	3	<input type="checkbox"/>
Reviewer Notes 14-JAN-2009	6	8	4	<input type="checkbox"/>
Acknowledgement Letter 24-DEC-2008	9	12	5	<input type="checkbox"/>
Total documents: 5				<input type="checkbox"/>
Total document pages: 12				<input type="checkbox"/>
Total separator pages: 5				<input type="checkbox"/>
Total Scan pages: 18				<input type="checkbox"/>

QC Signature _____

QC Bar Code Sticker



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 15 2009

Re: K083839
Trade/Device Name: Avaulta™ Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: December 16, 2008
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Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083839

1.4 Indications for Use Statement

510(k) Number (if known): _____

Device Name: Avaulta™ Support System

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(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)

Nial R. Ogle, Sr. M.D.
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083839

(Recommended Format 11/13/2003)



January 06, 2009

C.R. BARD, INC.
UROLOGICAL DIVISION
13183 HARLAND DRIVE
COVINGTON, GEORGIA 30014-6421
UNITED STATES
ATTN: TERRI MORRIS

510k Number: K083839

Received: 12/23/2008

Product: AVAULTA SOLO SYNTHETIC SUPPORT

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 24, 2008

C.R. BARD, INC.
UROLOGICAL DIVISION
13183 HARLAND DRIVE
COVINGTON, GEORGIA 30014-6421
UNITED STATES
ATTN: TERRI MORRIS

510k Number: K083839
Received: 12/23/2008
User Fee ID Number:
Product: AVAULTA SOLO SYNTHETIC S

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Pre-market Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

12

Bard Urological Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

KO 83839



December 16, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FDA CDRH DMC

DEC 23 2008

Re: Special Premarket 510(k) Notification
Avaulta Support System

Received

K-32

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, Bard Urological Division, C.R. Bard, Inc., is submitting two copies of this 510(k) notification of changes to Bard's Avaulta Support System and two copies of this cover letter. One copy of the 510(k) notification is being provided in electronic format per FDA's web instructions and is an exact duplicate of the paper copy. The purpose of this 510(k) submission is to notify FDA of a minor design change to the Avaulta Support System Implant.

Device Name:	Avaulta Support System
Trade Name(s):	Avaulta Solo™ Synthetic 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

FDA document numbers associated with this submission include the predicate 510(k), K063712 and a special 510(k), K082571.

The terms "substantially equivalent", "similar" and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

Exhibit 1 contains a copy of a completed CDRH Premarket Review Submission Cover Sheet. Section 1.0 contains Screening Checklists for Special Premarket Notification [510(K)] Submissions with references to the sections of this document that contain the required information, the Premarket Notification Truthful and Accurate Statement and the 510(k) Indications for Use Statement. The 510(k) Summary of Safety and Effectiveness Information can be found as Exhibit 2. The general design and use of the device is indicated in the table below:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from tissue or other biologic source?	X	
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does the device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

C. R. Bard, Inc. has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C. R. Bard, Inc. requests that FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b).

C. R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions about this notification, the Contact Person is:

Terri Morris
 terri.morris@crbard.com

678-342-4922
 770-788-5605 (fax)

I hereby authorize the FDA to communicate with me regarding this submission via phone, fax and/or email as indicated above. Thank you in advance for your consideration of our application.

Sincerely,



Terri Morris
 Regulatory Affairs Specialist II
 Bard Urological Division

Enclosures

Bard Urological Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014



December 16, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Special Premarket 510(k) Notification
Avaulta Support System

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Common/Usual Name:	Surgical Mesh
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Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
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Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

C. R. Bard, Inc. has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C. R. Bard, Inc. requests that FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b).

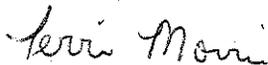
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If you have any questions about this notification, the Contact Person is:

Terri Morris	678-342-4922
terri.morris@crbard.com	770-788-5605 (fax)

I hereby authorize the FDA to communicate with me regarding this submission via phone, fax and/or email as indicated above. Thank you in advance for your consideration of our application.

Sincerely,



Terri Morris
Regulatory Affairs Specialist II
Bard Urological Division

Enclosures

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) C R BARD INC 13183 Harland Drive Covington GA 30014 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)	2. CONTACT NAME Terri Morris 2.1 E-MAIL ADDRESS terri.morris@crbard.com 2.2 TELEPHONE NUMBER (include Area code) 678-342-4922 2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-null	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma) Select an application type: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice 		
3.1 Select one of the types below <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Original Application Supplement Types: <ul style="list-style-type: none"> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) 		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <ul style="list-style-type: none"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially 		
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		11-Nov-2008

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

Special Premarket Notification [510(k)]

C.R. Bard, Inc.
Bard Urological Division (BUD)

Avaulta™ Support System

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Avaulta™ Support System

Special Premarket Notification [510(k)]

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EXHIBITS

Exhibit 1 – Regulatory Forms

Exhibit 2 – 510(k) Summary of Safety and Effectiveness

Exhibit 3 – Subject Device Drawings

Exhibit 4 – Risk Summary Table

Exhibit 5 – 510(k) Substantial Equivalence Decision Tree

Exhibit 6 – Declaration of Conformity with Design Controls

1.0 REGULATORY INFORMATION

1.1 Regulatory Forms

Exhibit 1 contains the following regulatory forms:

- FDA-3514: CDRH Premarket Review Submission Cover Sheet
- FDA-3674: Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank

1.2 Screening Checklists for Special Premarket Notification [510(K)] Submissions

Table 1.2.1: Required Elements for all Types of 510(k) Submissions

Required Element	Location
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual	Cover Letter
Table of Contents	Table of Contents
Truthful and Accurate Statement	Section 1.3
Device Trade Name, Device's Classification Name and Establishment Registration Number	Section 2.2
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Section 2.2
Proposed Labeling including the materials listed on page 3-4 of the Premarket Notification [510(k)] Manual.	N/A (No changes affecting labeling)
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 1.4
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Section 3.3
510(k) Summary	Exhibit 2
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Exhibit 3
Identification of legally marketed predicate device.	Section 2.2
Compliance with performance standards.	Section 2.2
Class III Certification and Summary	N/A (Class II Device)
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. [See 21 CFR 807.87(l)]	N/A (No clinical studies)
510(k) Kit Certification	N/A (No changes affecting kit)

Table 1.2.2: Additional Requirements for a SPECIAL 510(k) Submissions

Required Element	Location
Name and 510(k) number of the sponsor's own, unmodified predicate device.	Section 2.2
A description of the modified device and a comparison to the sponsor's predicate device.	Section 3.0
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.	Sections 2.3 and 2.4
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	Section 3.1
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 1.4
A design Control Activities Summary that includes the following elements (a-c below):	
<ul style="list-style-type: none"> a. Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. 	Section 4.3
<ul style="list-style-type: none"> b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. 	Sections 4.3 and 4.4
<ul style="list-style-type: none"> c. A Declaration of Conformity with design controls that includes the following statements: 	Exhibit 6
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities. 	Exhibit 6
<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities. 	Exhibit 6

1.3 Premarket Notification Truthful and Accurate Statement

I certify that, in my capacity as Regulatory Affairs Specialist of C.R. Bard, Inc., Bard Urological Division I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been omitted.

Signature: Terri L. Morris

Typed Name: Terri Morris
Regulatory Affairs Specialist II

Date: 12-15-08

510(k) Number:
(if applicable) _____

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
(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)

(Recommended Format 11/13/2003)

2.0 INTRODUCTION

2.1 Purpose of Premarket Notification

The purpose of this Special 510(k) submission is to notify FDA of a colorant change to the Avaulta Solo™ Synthetic Support System and Avaulta Plus™ Biosynthetic Support System. These devices are covered under K063712 and K082571.

The modified Avaulta Support Systems have the same intended use, general design, materials and fundamental scientific technology as the predicate device. The decision tree and guidance included in *The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications* was used to determine that a Special 510(k) is appropriate for these changes.

2.2 General Information

Subject Device Information

Device Name: Avaulta Support System
Trade Name(s): Avaulta Solo™ Synthetic 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

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, where applicable, adherence to the following guidance has been maintained:

- Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, issued March 2, 1999

Predicate Device Information

Device Name: Avaulta Support System
Trade Name(s): Avaulta Solo™ Synthetic 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
Premarket Notification: K063712, clearance date – March 12, 2007
K082571, clearance date – September 30, 2008

Manufacturer/Submitter

Manufacturer Name: Bard Urological Division (BUD)
[a division of C.R. Bard, Inc.]
Address: 13183 Harland Drive
Covington, GA 30014
Contact Person: Terri Morris
Telephone Number: 678-342-4922
Fax Number: 770-788-5605
Registration Number: 1018233
Additional Registration Numbers:
C.R. Bard: 2212754

Sterilization Sites

Name: Bard Medical Division (BMD)
[a division of C.R. Bard, Inc.]
Address 1: 8195 Industrial Blvd.
Covington, GA 30014
Registration Number: 1018233
Address 2: 1211 Mary Magnan Blvd.
Madison, GA 30650
Registration Number: 3006082230

2.3 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.

The intended use has not changed.

2.4 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.

The indications for use have not changed.

2.5 Device History

No device modifications have been made to the Avaulta Support System since the submission of K082571.

3.0 DEVICE DESCRIPTION

3.1 Device Principles of Operation

As explained in K063712, the Avaulta Support System includes a sterile, single use, permanent implant that provides long term reinforcement to support structures in the correction of 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. Each implant is accompanied by a sterile, single use, Class I, Exempt introducer used for placement of the implant.

The Avaulta Support System is offered in multiple configurations:

- Avaulta Solo Synthetic Support System for Anterior Repair
- Avaulta Solo Synthetic Support System for Posterior Repair
- Avaulta Plus Biosynthetic Support System with Porcine Graft for Anterior Repair
- Avaulta Plus Biosynthetic Support System with Porcine Graft for Posterior Repair

The fundamental technology of the implant has not changed.

3.2 Device Design and Materials

The Avaulta Solo™ Synthetic Support System implant is composed of a pre-cut synthetic mesh implant. The Avaulta Plus™ Biosynthetic Support System implant is composed of the same pre-cut synthetic mesh implant with a porcine collagen sheet covering one side of the central section. The devices each have a belly section and four support arms. To facilitate surgeon implantation, the midline of the belly and one (Posterior) and two (Anterior) of the support arms have a colored marker composed of blue polypropylene fiber sewn into their structure. Please refer to Exhibit 3 for drawings of the devices. All materials and their regulatory status are identified in the following table:

Component	Material	Historical Clearance
Central soft mesh, lateral strong mesh and sewing fiber (for collagen attachment)	Natural polypropylene monofilament fiber	K051503 – Sofradim UGYTEX Dual Knit Mesh (predicate) K052155 – Bard Soft Mesh K063712 – Avaulta Plus™ and Avaulta Solo™ Support System
Central and lateral colored markers	Blue polypropylene monofilament fiber	K081010 – Bard 3D MAX Mesh
Collagen sheet	Lyophilized, crosslinked, acellular, porcine dermal collagen	K052322 – Bard CollaMend Implant (predicate) K063712 – Avaulta Plus™ and Avaulta Solo™ Support System

The overall design, including device materials, performance specifications and dimensional specifications, has not changed.

3.3 Design Modifications Addressed In This Submission

The supplier of the blue polypropylene fiber used for the colored marker is being changed. The new supplier also uses polypropylene as the base material but uses a different colorant. In addition to the change in colorant, there will be a slight change to the dimensions of the blue polypropylene fiber; however, there are no changes to the overall dimensions of the mesh implant itself.

The following table provides a comparison between the predicate and subject devices.

NOTE: Bold Type – Indicates a difference between predicate as currently marketed and subject device.

Plain Type – Indicates the subject device attribute is the same as that of the predicate device as currently marketed.

Attribute	Predicate Device Avaulta Support System K063712 and K082571	Subject Device Avaulta Support System
Intended Use	Reinforcement of tissue during surgical repair.	Same
Indications for Use	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.	Same
Mesh central section	Avaulta Solo: Soft knit mesh Avaulta Plus: Soft knit mesh with porcine collagen sheet fully attached to one side of the mesh except for the distal 3cm on the posterior implant	Same
Mesh colored markers	Blue polypropylene markers on the midline and in lateral arms, (b) (4)	Blue polypropylene markers on the midline and in lateral arms, (b) (4)
Dimensions of the Mesh colored markers	Suture 5-0: (b) (4) Suture 6-0: (b) (4)	(b) (4) (b) (4)
Mesh lateral arms	Strong knit mesh	Same
Mesh characteristics	Porous, open, monofilament knit that allows trimming of the implant and tissue ingrowth	Same
Collagen	Crosslinked, acellular, lyophilized porcine dermal collagen sheet	Same
Collagen thickness	0.5mm	Same
Collagen porosity	1.8mm holes	Same
Implant shape	Precut for anterior and posterior repair with apical flap on both	Same
Implant method of fixation	Staples, sutures or tension free	Same
Implant sterilization	EtO	Same

3.4 Packaging

There are no changes to packaging. The Avaulta Implant is packaged in a thermoformed blister tray with a Tyvek® lid. The sealed tray is placed in one of two pouches:

- The Avaulta Plus synthetic/collagen implant tray is placed in a foil/foil pouch with a Tyvek® header. After sterilization, the pouch is sealed below the Tyvek® header (i.e. foil to foil) which is then removed. The foil pouch with foil to foil heat seal provides a long-term moisture barrier while maintaining sterility of the contents.
- The Avaulta Solo synthetic implant tray is placed in Tyvek®/film pouch.

The packaged implant and separately packaged Class I, Exempt introducer are placed in a corrugate box.

3.5 Sterilization

There are no changes to the sterilization method or cycle. The Avaulta Support System is supplied as a sterile, single use device sterilized by EtO with an SAL (Sterility Assurance Level) of 1×10^{-6} at the C.R. Bard, Inc. facilities in Covington and Madison, Georgia.

Ethylene Oxide (EtO) residues remaining on the product must be within the limits for a permanent exposure device per ANSI/AAMI/ISO 10993-7:1995 and TIR No. 19-1998. C.R. Bard, Inc. follows the ISO guidance in that the maximum ethylene oxide dose shall not exceed 20mg in the first 24 hours of use. The concentration of ethylene oxide shall not exceed 250ppm. The maximum ethylene chlorohydrin dose shall not exceed 12mg in the first 24 hours.

3.6 Stability

There are no changes to the shelf life of the device. The Avaulta Support System is offered with a 2 year shelf life. This is based on accelerated aging studies conducted on polypropylene mesh which demonstrate a 5 year shelf life and real time aging studies conducted on the Collamend Implant (Collamend was the original predicate device for the Collagen sheet referenced in K063712 upon which shelf life was determined) which demonstrate a 2 year shelf life. In addition, accelerated aging simulating two years of real-time aging is being conducted on the modified device mesh to ensure that the device will maintain the necessary operational characteristics over time.

3.7 Labeling

There have been no changes to the labeling since the submission and clearance of K082571.

Labeling is the same for the modified and predicate devices.

4.0 Summary of Design Control Activities

4.1 User Needs

The change in the supplier and colorant for the blue polypropylene fiber will be invisible to the end user and is the result of a cost savings initiative. This change did not generate any new user needs.

4.2 Design Inputs

The change in the supplier and colorant for the blue polypropylene fiber will be invisible to the end user and is the result of a cost savings initiative. This change did not generate any new design inputs.

4.3 Risk Analysis

As indicated in K063712 and K082571, a design failure modes and effects analysis (DFMEA) of the Avaulta Plus Implant was conducted in accordance with an internal procedure based on EN/ISO 14971 *Medical Devices – Application of Risk Management to Medical Devices* to assure that risks posed by the device are acceptable. The analysis of the change to the colorant did not raise any new types of safety or effectiveness questions. All known risks posed by the blue fiber are currently addressed in the existing DFMEA; therefore, no update to the existing risk analysis was required.

4.4 Summary of Design Verification and Validation Activities

The materials of construction, manufacturing methods, performance specifications and overall design of the Avaulta Support System Implant have not changed. In addition, the intended use of the device remains the same and the sterilization process remains the same for both the modified and predicate devices. The only change is to the supplier and colorant used for the blue polypropylene fiber. Because there were no new types of safety or effectiveness questions, no design verification tests were required to specifically address any risks identified. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," the following design verification activities were conducted: Visual, dimensional, ball burst strength, suture pullout and tensile strength. The testing demonstrated that the modified device was substantially equivalent to the predicate and met the predetermined acceptance criteria. Refer to Exhibit 4 for the Risk Summary Table.

Biocompatibility of the new blue polypropylene fiber was established by Bard Davol Division via testing carried out on the 3D MAX Mesh product under K081010, clearance date October 7, 2008. The biological testing profile carried out for the 3D MAX mesh was for permanent implantation with tissue/bone contact which is identical to the tissue contact profile for the Avaulta Support System. The natural fiber and the blue fiber used in both the Davol 3D Max Mesh and the Avaulta Support System are comprised of the same materials. The only difference is the

size of the fibers used. Therefore, on the basis of acceptable biological data for the 3D Max Mesh, the Avaulta Support System also meets the requirements of ISO 10993 Biological Evaluation of medical devices to establish biocompatibility for the devices' intended use.

4.5 Conclusion

The subject Avaulta Support System has been evaluated in both design verification and validation tests and determined to meet all predetermined acceptance criteria and is substantially equivalent to the predicate device.

5.0 SUBSTANTIAL EQUIVALENCE

BUD intends to modify the Avaulta Support System originally cleared under K063712 and K082571.

The "510(k) Substantial Equivalence Decision Making Process (Detailed) Decision Tree" was used in determining the substantial equivalence of the Avaulta Support System implant to the predicate device.

A copy of this decision tree is provided as Exhibit 5. Additionally, the answers to the following questions on the decision tree confirm substantial equivalence to the predicate device.

1. Does new device have same indication statements?

Yes. The indications for use statement has not changed.

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.

3. Does new device have same technological characteristics, e.g., design, materials, etc.?

No. The subject and predicate device have the same general design features and rely on the same fundamental scientific technology; however the subject Avaulta Support System incorporates a colorant change to the blue polypropylene fiber used as a marker within the mesh which facilitates surgeon implantation.

4. Could the new characteristics affect safety or effectiveness?

Yes. The colorant change could affect safety and effectiveness.

6. Do the new characteristics raise new types of safety or effectiveness questions?

No. Both the subject and predicate device perform their intended function in the same manner using the same fundamental scientific technology.

7. Do accepted scientific methods exist for assessing effects of new characteristics?

Yes. Functional performance has been addressed by conducting relevant testing as determined by the initial risk analysis and in consideration of FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," as appropriate. Biocompatibility has been addressed through adherence to ISO 10993.

8. Are performance data available to assess effects of new characteristics?

Yes. Design verification and validation activities have been summarized herein. Biocompatibility testing was reported under K081010, clearance date October 7, 2008.

9. Performance data demonstrate equivalence?

Yes. The testing summarized herein demonstrates that the subject device met all predetermined acceptance criteria and is substantially equivalent to the predicate.

Based on the answers to the above questions, the subject Avaulta Support System is substantially equivalent to the predicate Avaulta Support System (K063712 and K082571).

Exhibit 1

Regulatory Forms

- FDA-3514: CDRH Premarket Review Submission Cover Sheet
- FDA-3674: Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 9/3/2008	User Fee Payment ID Number MD6036608-956733	FDA Submission Document Number (if known)
--------------------------------	--	---

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name C.R. Bard, Inc.	Establishment Registration Number (if known) 1018233		
Division Name (if applicable) Bard Urological Division (BUD)	Phone Number (including area code) (678) 342-4922		
Street Address 13183 Harland Drive	FAX Number (including area code) (770) 788-5605		
City Covington	State / Province GA	ZIP/Postal Code 30014	Country USA
Contact Name Terri Morris			
Contact Title Regulatory Affairs Specialist II		Contact E-mail Address terri.morris@crbard.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
 - Software / Hardware
 - Color Additive
 - Material
 - Specifications
 - Other (*specify below*)

- Location change:
 - Manufacturer
 - Sterilizer
 - Packager

- Process change:
 - Manufacturing
 - Sterilization
 - Packaging
 - Other (*specify below*)

- Labeling change:
 - Indications
 - Instructions
 - Performance
 - Shelf Life
 - Trade Name
 - Other (*specify below*)

- Report Submission:
 - Annual or Periodic
 - Post-approval Study
 - Adverse Reaction
 - Device Defect
 - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (*specify*):

SECTION D2

REASON FOR APPLICATION - IDE

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
 - Correspondent / Applicant
 - Design / Device
 - Informed Consent
 - Manufacturer
 - Manufacturing Process
 - Protocol - Feasibility
 - Protocol - Other
 - Sponsor

- Report submission:
 - Current Investigator
 - Annual Progress Report
 - Site Waiver Report
 - Final

- Repose to FDA Letter Concerning:
 - Conditional Approval
 - Deemed Approved
 - Deficient Final Report
 - Deficient Progress Report
 - Deficient Investigator Report
 - Disapproval
 - Request Extension of Time to Respond to FDA
 - Request Meeting
 - Request Hearing

- Other Reason (*specify*):

SECTION D3

REASON FOR SUBMISSION - 510(k)

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (*specify*):
Change in Colorant

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	79 FTL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K063712	1	Avaulta Support System	1	C.R. Bard, Inc.
2	K082571	2	Avaulta Support System	2	C.R. Bard, Inc.
3	K081010	3	3-D Max Mesh	3	C.R. Bard, Inc.
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Surgical Mesh

	Trade or Proprietary or Model Name for This Device		Model Number
1	Avaulta Support System	1	Multiple
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code 79 FTL	C.F.R. Section (if applicable) 21 CFR 878.3300	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)

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.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 1018233	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name C.R. Bard, Inc.		Establishment Registration Number 1018233		
Division Name (if applicable) Bard Urological/Medical Division		Phone Number (including area code) (678) 342-4820		
Street Address 8195 Industrial Blvd.		FAX Number (including area code) () N/A		
City Covington		State / Province GA	ZIP/Postal Code 30014	Country USA
Contact Name Al Jacks		Contact Title Vice President, QA/RA		Contact E-mail Address al.jacks@crbard.com

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3006082230	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name C.R. Bard, Inc.		Establishment Registration Number Pending		
Division Name (if applicable) Bard Medical Division		Phone Number (including area code) (770) 784-6120		
Street Address 1211 Mary Magnan Blvd.		FAX Number (including area code) (770) 784-6340		
City Madison		State / Province GA	ZIP/Postal Code 30650	Country USA
Contact Name Mary Mayo		Contact Title Staff Vice President, Quality Assurance		Contact E-mail Address mary.mayo@crbard.com

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3005636544	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name C.R. Bard, Inc.		Establishment Registration Number 3005636544		
Division Name (if applicable) Bard Shannon Limited		Phone Number (including area code) (787) 656-5500		
Street Address San Geronimo Industrial Park, Lot #1, Road #3, km 79.7		FAX Number (including area code) () N/A		
City Humacao		State / Province PR	ZIP/Postal Code 00791	Country USA
Contact Name Gary Lopez		Contact Title Plant QA Manager		Contact E-mail Address gary.lopez@crbard.com

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Exhibit 2

510(k) Summary of Safety and
Effectiveness

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.
Address:	Bard Urological Division 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 FTL – Mesh, Surgical, Polymeric
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

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).

Exhibit 3

Subject Device Drawings

ANTERIOR PRE-CUT CONFIGURATION

(b) (4)

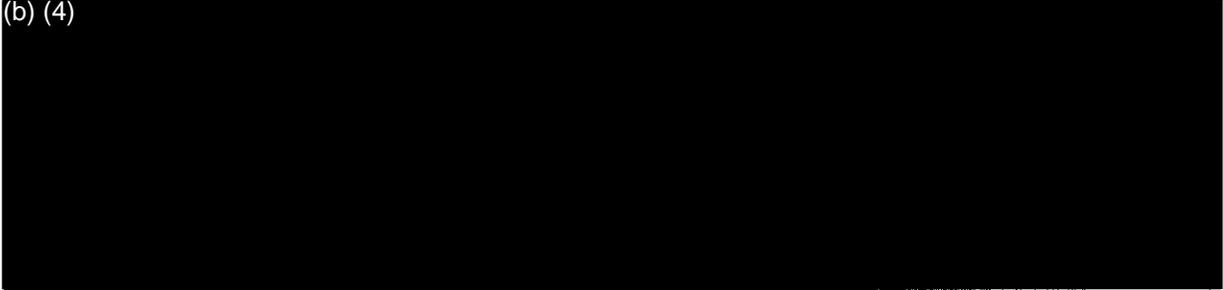
A large rectangular area of the document is completely redacted with a solid black box.

Figure 1: Dimensions (b) (4)

(b) (4)

A large rectangular area of the document is completely redacted with a solid black box.

Figure 2: Avaulta Solo Synthetic Support System

(b) (4)

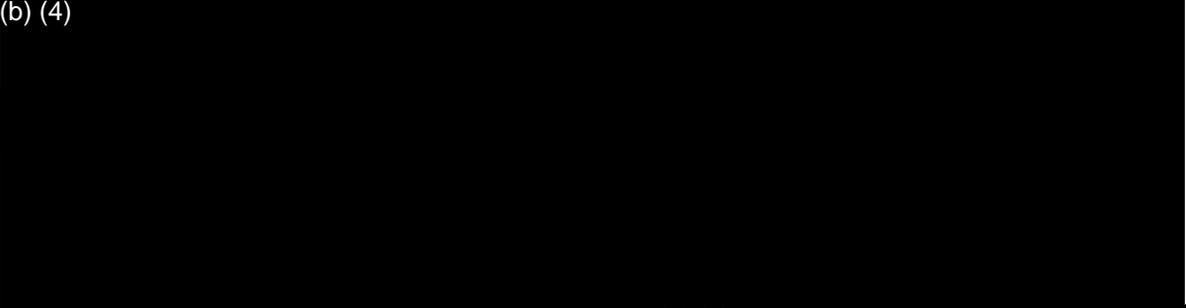
A large rectangular area of the document is completely redacted with a solid black box.

Figure 3: Avaulta Biosynthetic Support System (b) (4)

POSTERIOR CONFIGURATION

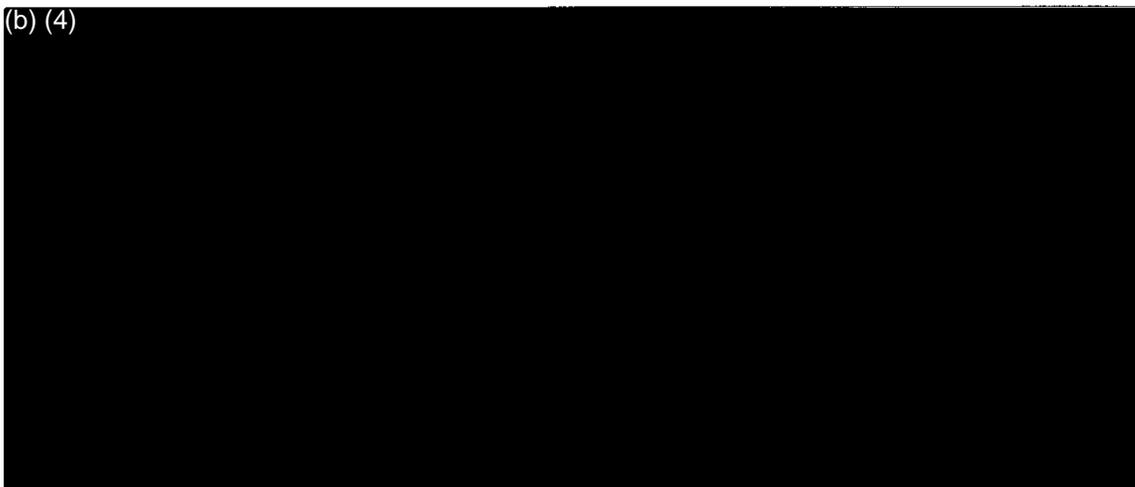


Figure 4: Avaulta Plus and Solo Implant Dimensions (b) (4)

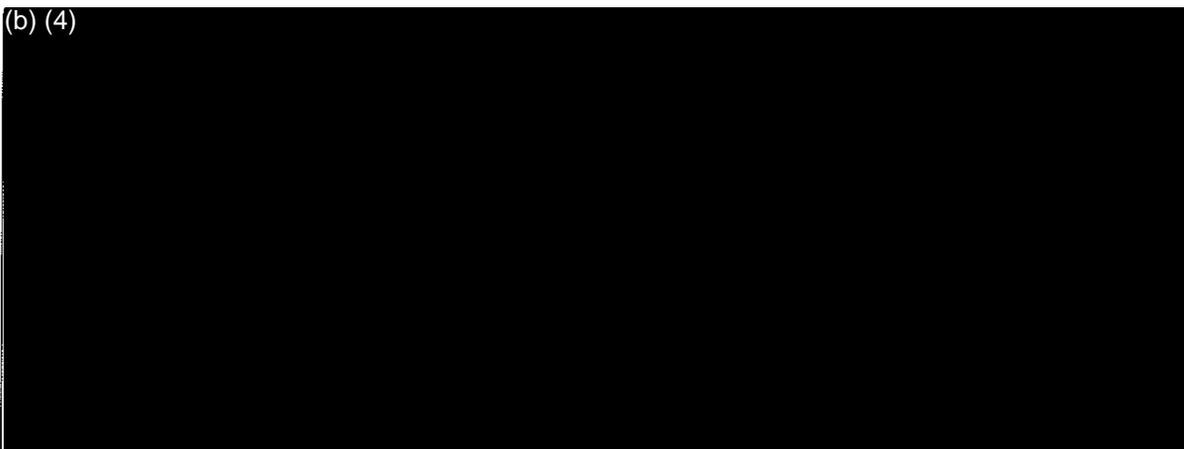


Figure 5: Avaulta Solo Synthetic Support System

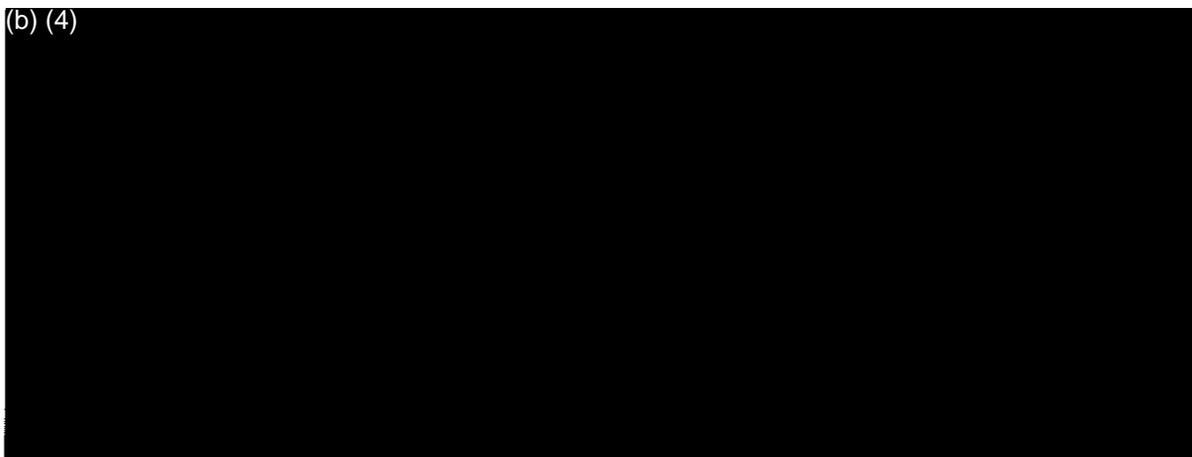


Figure 6: Subject Posterior Avaulta Plus Biosynthetic Support System (b) (4)

Exhibit 4

Risk Summary Table

Avaulta™ Support System Blue Fiber - Risk Summary Table

Technical Feature	Original Design	Change	Potential Risk	Mitigation of Risk	Acceptance Criteria	Result/Outcome
(b) (4)				(b) (4)		

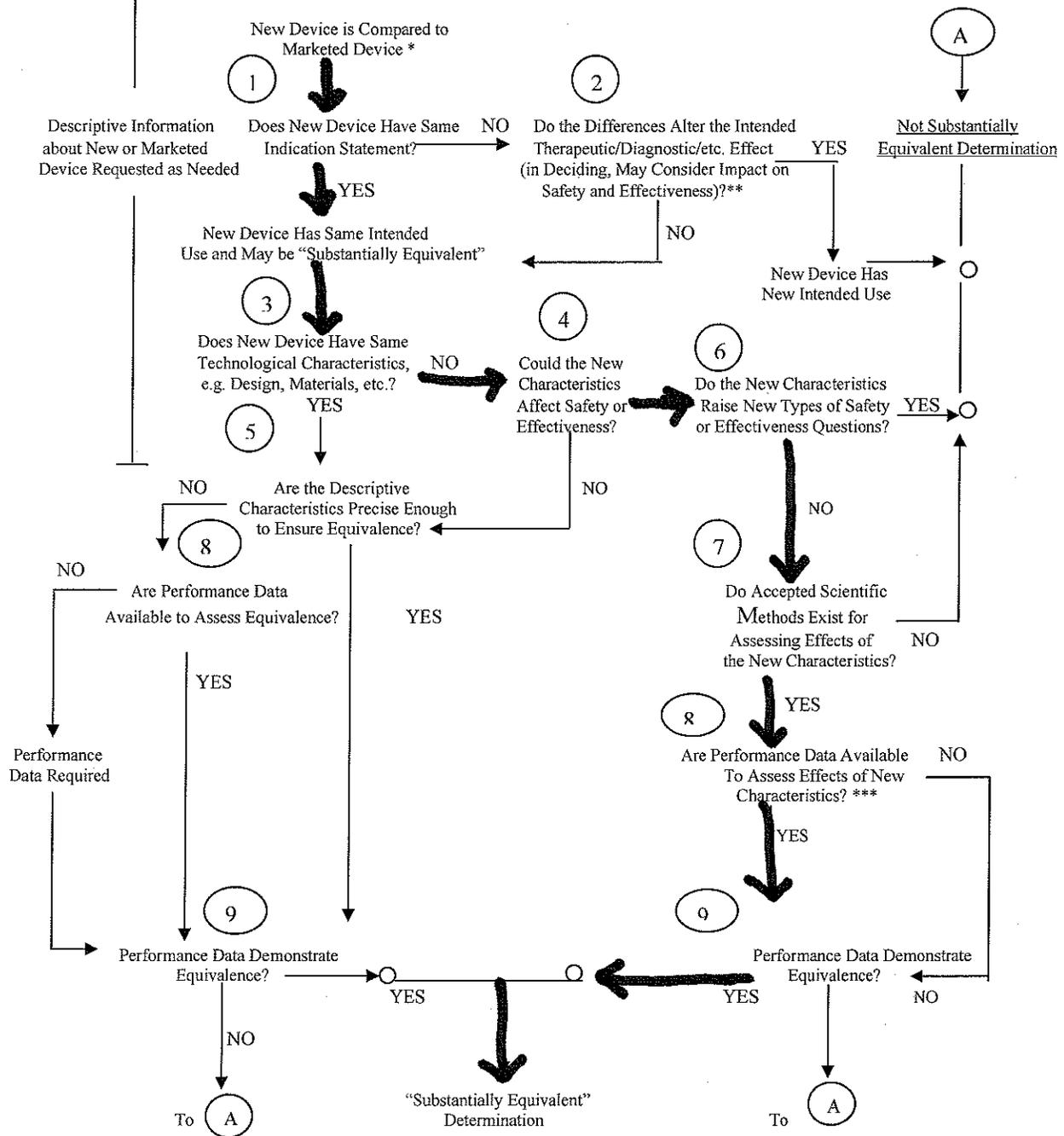
Avaulta™ Support System Blue Fiber - Risk Summary Table

Technical Feature	Original Design	Change	Potential Risk	Mitigation of Risk	Acceptance Criteria	Result/Outcome
(b) (4)						

Exhibit 5

510(k) Substantial Equivalence Decision Tree

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

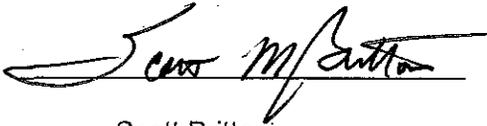
*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Exhibit 6

Declaration of Conformity
with Design Controls

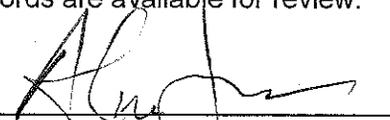
DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

I certify that, in my capacity as Vice President of Research and Development of Bard Urological Division, I believe to the best of my knowledge, that as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met.

Signature:  Date: 12/18/08

Typed Name: Scott Britton
Vice President of Research and Development

I certify that, in my capacity as Vice President of Quality Assurance and Regulatory Affairs of Bard Urological Division, I believe to the best of my knowledge, that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Signature:  Date: 12-18-08

Typed Name: Al Jacks
Vice President of Quality Assurance and Regulatory Affairs



COVER SHEET MEMORANDUM

From: Reviewer Name Clifford Ph.D.
Subject: 510(k) Number 1083839
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary / 510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision	NA	
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?		X	
All Pediatric Patients age <= 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 -< 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			X

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input checked="" type="checkbox"/>

Regulation Number 878.3300 Class* II Product Code FTL
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Daniel Krane PASB 1/14/2009
 (Branch Chief) (Branch Code) (Date)

Final Review: Neil R. O'Neil for mxn 1/14/09
 (Division Director) (Date)

5

To: THE FILE

RE: DOCUMENT NUMBER K083839

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: Avaulta Support System, Avaulta Solo™ Synthetic Support System, Avaulta Plus™ Biosynthetic Support System (K063712, K082571).
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** (pg. 6) along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed** (pg. 7).

(b) (4)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical and characteristics. The changes will have little influence on the mesh dimensional or performance characteristics. The (b) (4) [redacted] has been used in the sponsor's Bard 3DMAX Mesh predicate (K081010).

Device Name: **Bard 3DMAX Mesh**

Indications for Use: The Bard 3DMAX Mesh is a sterile, single use device indicated to reinforce soft tissue where weakness exists e.g. for repair of hernias and chest wall defects.

I concur,
Daniel Krone
1/14/2009

I concur,
Neil Sorenson
1/14/09

The Bard 3DMAX is a surgical mesh similarly constructed (b) (4) and which contains (b) (4) (from K081010):

The modified Bard 3DMAX Mesh is anatomically designed to fit the inguinal anatomy. (b) (4)

(b) (4)

5. A **Design Control Activities Summary** which includes (Exhibit 4):
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
 - c) A declaration of conformity with design controls (Exhibit 6). The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement** (pg. 3), a **510(k) Summary** (Exhibit 2) and the **Indications for Use Enclosure** (pg. 4).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the

design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Al Guda, Ph.D.
(Reviewer's Signature)

1/14/09
(Date)