USER: JOHNSON, SHEVON E (sxj)

FOLDER: K063712 - 140 pages (FOI:09003750)

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

PRODUCT: MESH, SURGICAL, POLYMERIC (FTL)

SUMMARY: Product: AVAULTA SUPPORT SYSTEM/AVAULTA PLUS BIOSYNTHETIC SUPPORT SYSTEM

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

DATE PRINTED: Fri Jan 14 06:03:42 2011

Note: Releasable Version

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

MAR 12 2007

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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 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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR 12 2007

Re: K063712
Trade/Device Name: Avaulta™ Solo Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 8, 2006
Received: December 14, 2006

Dear Mr. Knorpp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (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/industry/support/index.html.

Sincerely yours,

for Pedro Rivera

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

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 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)

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

510(k) Number K063712

(Recommended Format 11/13/2003)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR 12 2007

Re: K063712
Trade/Device Name: Avaulta™ Solo Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 8, 2006
Received: December 14, 2006

Dear Mr. Knorpp:

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.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (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/industry/support/index.html.

Sincerely yours,

for Paul Rumm

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

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 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)

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

510(k) Number K063712

(Recommended Format 11/13/2003)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 20, 2006

C.R. BARD, INC.
BARD UROLOGICAL DIVISION (BUD)
13183 HARLAND DRIVE
COVINGTON, GA 30014
ATTN: JOHN C. KNORPP

510(k) Number: K063712
Received: 14-DEC-2006
Product: AVAULTA SUPPORT SYSTEM

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.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 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). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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/elecsub.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 policy or procedural questions, please contact anyone on the 510(k) Staff at (240)276-4040.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 14, 2006

C.R. BARD, INC.
BARD UROLOGICAL DIVISION (BUD)
13183 HARLAND DRIVE
COVINGTON, GA 30014
ATTN: JOHN C. KNORPP

510(k) Number: K063712
Received: 14-DEC-2006
Product: AVAULTA SUPPORT
User Fee ID Number: M

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 Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	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/elecsub.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-fee 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 Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

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

K063712

BARD

December 8, 2006

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

Re: **Traditional Premarket 510(k) Notification**
Avaulta Support System

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 for Bard's Avaulta Support System and two copies of this cover letter.

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.

Section 1.0 contains a copy of a completed CDRH Premarket Submission Cover Sheet, the Premarket Notification Truthful and Accurate Statement, the 510(k) Indications for Use Statement, and Screening Checklists for Premarket Notification [510(K)] Submissions with references to the Sections of this document that contains the required information. The 510(k) Summary of Safety and Effectiveness Information can be found as Exhibit 2.

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:

John C. Knorpp	678-342-4920
john.knorpp@crbard.com	770-788-5513 (fax)

I hereby authorize the FDA to communicate with me regarding this submission via phone,

SI
II
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fax and/or email as indicated above. Thank you in advance for your consideration of our application.

Sincerely,

John C. Knorpp, RAC
Manager, Regulatory Affairs
Bard Urological Division

Enclosures

Traditional Premarket Notification [510(k)]

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

Avaulta™ Support System

TABLE OF CONTENTS

Avaulta Support System

Traditional Premarket Notification [510(k)]

EXHIBITS

1.0 REGULATORY INFORMATION

1.1 CDRH Submission Coversheet

CDRH SUBMISSION COVER SHEET

Date of Submission: **December 8, 2006** | FDA Document Number:

Section A Type of Submission

PMA	**PMA Supplement**	**PDP**	**510(k)**	**Meeting**
☐ Original submission ☐ Modular submission ☒ Amendment ☐ Report ☐ Report Amendment	☒ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Pre-submission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☒ Amendment to PDP ☒ Report	Original Submission: ☒ **Traditional** ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify)
IDE ☐ Original submission ☐ Amendment ☐ Supplement	**Humanitarian Device Exemption** ☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	**Class II Exemption** ☐ Original submission ☐ Additional information	**Evaluation of Automatic Class III Designation** ☐ Original submission ☐ Additional information	**Other Submission** Describe Submission:

Section B Applicant or Sponsor

Company / Institution name: **C. R. Bard, Inc.**		Establishment registration number: **1018233**	
Division Name (if applicable): **Bard Urological Division (BUD)**		Phone Number (include area code): **678-342-4920**	
Street Address: **13183 Harland Drive**		Fax Number (include area code): **770-788-5513**	
City: **Covington**	State/Province: **Georgia**	Zip code: **30014**	Country: **USA**
Contact Name: **John C. Knorpp**			
Contact Title: **Manager, Regulatory Affairs**		Contact e-mail address: **john.knorpp@crbard.com**	

Section C Submission correspondent (if different from above)

Company/Institution Name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street Address:		Fax Number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact Name:			
Contact Title:		Contact e-mail address:	

Section D1 Reason for Submission – PMA, PDP, or HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Licensing Agreement
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Processing Change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Labeling Change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other (specify below)
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post Approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Other Reason (specify)
- ☐ Change in Ownership
- ☐ Change in correspondent

Section D2 Reason for Submission – IDE

- ☐ New Device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergence use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):

Change in:

- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol-feasibility
- ☐ Protocol-other
- ☐ Sponsor

- ☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

- ☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

Section D3 Reason for Submission – 510(k)

- ☒ New Device
- ☐ Additional or expanded indications
- ☐ Other reason (specify): Line Extension
- ☐ Change in technology
- ☐ **Change in design**
- ☐ **Change in materials**
- ☐ Change in manufacturing process

Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1	2	3	4
79 FTL			
5	6	7	8

Summary of, or statement concerning safety and effectiveness data:
- ☒ **510(k) summary attached**
- ☐ 510(k) statement

510(k) Number	Trade or Proprietary or model name:	Manufacturer
1 **K051503**	1 **UGYTEX® Dual Knit Mesh**	1 **Sofradim Production**
2	2	2
3	3	3

Section F Product Information -- Applicable to All Applications					
Common or usual name or classification name: **Surgical Mesh**					
Trade or proprietary or model name			Model Number		
1 **Avaulta Support System**			1 **Multiple**		
2			2		
3			3		
4			4		
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 – Applicable to All Applications		
Product code: **79 FTL**	CFR Section: **21 CFR 878.3300**	Device Class: ☐ Class I ☒ **Class II** ☐ Class III ☐ 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:**	
Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission			
☒ **Original** ☐ Add ☐ Delete	FDA Establishment registration number: **1018233**	☒ **Manufacturer** ☐ Contract Manufacturer	☒ **Contract Sterilizer** ☐ Repackager/relabeler
Company/Institution name: **C. R. Bard, Inc.**		Establishment registration number: **1018233**	
Division name (if applicable): **Bard Urological/Medical Division**		Phone number (include area code): **678-342-4808**	
Street address: **8195 Industrial Blvd.**		Fax number (include area code): **678-342-4992**	
City: **Covington**	State/Province: **GA**	Zip code: **30014**	Country: **USA**
Contact name: **Frances Harrison**			
Contact title: **Vice President, Regulatory Affairs**			
☒ **Original** ☐ Add ☐ Delete	FDA Establishment registration number: **Pending**	☐ Manufacturer ☐ Contract Manufacturer	☒ **Contract Sterilizer** ☐ Repackager/relabeler
Company/Institution name: **C. R. Bard, Inc.**		Establishment registration number: **Pending**	
Division name (if applicable): **Bard Medical Division**		Phone number (include area code): **770-784-6120**	
Street address: **1211 Mary Magnan Blvd.**		Fax number (include area code): **770-784-6340**	
City: **Madison**	State/Province: **GA**	Zip code: **30650**	Country: **USA**
Contact name: **Mary Mayo**			
Contact title: **Staff Vice President, Quality Assurance**			
☒ **Original** ☐ Add ☐ Delete	FDA Establishment number: **3005636544**	☐ Manufacturer ☒ **Contract Manufacturer**	☐ Contract Sterilizer ☐ Repackager/relabeler
Company/Institution name: **C. R. Bard, Inc.**		Establishment registration number: **3005636544**	
Division name (if applicable): **Bard Shannon Limited**		Phone number (include area code): **787-656-5500**	
Street address: **San Geronimo Industrial Park, Lot #1, Road #3, km 79.7**		Fax number (include area code): **N/A**	
City: **Humacao**	State/Province: **Puerto Rico**	Zip code: **00791**	Country: **Puerto Rico**
Contact name: **Dan Gregoire**			
Contact title: **Plant QA Manager**			

☒ **Original** ☐ Add ☐ Delete	FDA Establishment number: **N/A**	☐ Manufacturer ☒ **Contract Manufacturer**	☐ Contract Sterilizer ☐ Repackager/relabeler
Company/Institution name: (b) (4)		Establishment registration number: **N/A**	
Division name (if applicable): **N/A**		Phone number (include area code): (b) (4)	
Street address: (b) (4)		Fax number (include area code): (b) (4)	
City: (b) (4)	State/Province: (b) (4)	Zip code: (b) (4)	Country: **USA**
Contact name: (b) (4)			
Contact title: **President**			

1.2 Premarket Notification Truthful and Accurate Statement

I certify that, in my capacity as Manager, Regulatory Affairs 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: 

Typed Name: John C. Knorpp
Manager, Regulatory Affairs

Date: 11-13-06

510(k) Number: _____
(if applicable)

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)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Recommended Format 11/13/2003)

1.4 Screening Checklists For Traditional Premarket Notification [510(K)] Submissions

Table 1.4.1: 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 1.2
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.	Exhibit 4
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 1.3
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.	Exhibit 6 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	Exhibit 9

Table 1.4.2: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) Submissions

Required Element	Location
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Section 4.1 Exhibit 7
b) Sterilization and expiration dating information:	Section 3.4.3 Section 3.4.4
i) sterilization process	3.4.3
ii) validation method of sterilization process	3.4.3
iii) SAL	3.4.3
iv) packaging	3.4.2
v) specify pyrogen free	N/A (No potential for systemic exposure to endotoxins*)
vi) ETO residues	3.4.3
vii) radiation dose	N/A (EtO)
c) Software Documentation:	N/A (No Software)

*Per FDA consensus standard ANSI/AAMI ST72:2002.

2.0 INTRODUCTION

2.1 Purpose of Premarket Notification

The purpose of this 510(k) submission is to notify FDA of the Avaulta™ Support System which contains a surgical implant used in the repair of vaginal wall prolapse. The predicate device is the Sofradim Production UGYTEX® Dual Knit Mesh (K051503). Both predicate and subject devices have the same intended use, fundamental scientific technology and general design. The subject device utilizes a porcine collagen sheet over the central soft knit section rather than the porcine collagen film on the predicate device. The porcine collagen sheet has been cleared under K052322, Bard® CollaMend™ Implant.

2.2 General Information

Subject Device Information

Device Name:	Avaulta Support System
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

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 and third party, FDA recognized consensus standard has been maintained:

- Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, issued March 2, 1999
- Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), issued November 6, 1998
- ISO 10993 – Biological Evaluation of Medical Devices

Predicate Device Information

Device Name:	UGYTEX® Dual Knit Mesh (Marketed as Avaulta™ Biosynthetic Support System)
Trade Names:	UGYTEX® Dual Knit Mesh
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:	K051503, clearance date – August 5, 2005.

Device Name:	Bard® CollaMend™ Implant
Trade Names:	Bard® CollaMend™ Implant
Common/Usual Name:	Surgical Mesh
Classification Names:	79 FTM – Mesh, Surgical
CFR Reference:	21 CFR 878.3300
Classification Panel:	General and Plastic Surgery
Premarket Notification:	K052322, clearance date – April 10, 2006.

Manufacturer/Submitter

Manufacturer Name:	Bard Urological Division (BUD) [a division of C.R. Bard, Inc.]
Address:	13183 Harland Drive Covington, GA 30014
Contact Person:	John C. Knorpp
Telephone Number:	678-342-4920
Fax Number:	770-788-5513
Registration Number:	1018233
Additional Registration Numbers:	
C.R. Bard:	2212754

Sterilization Sites

Manufacturer 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:	Pending

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 for the subject Avaulta Support System is the same as the predicate UGYTEX Dual Knit Mesh.

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 the subject Avaulta Support System is the same as the predicate UGYTEX Dual Knit Mesh.

3.0 DEVICE DESCRIPTION

3.1 Device Principles of Operation

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. Each implant is accompanied by a sterile, single use, Class I, Exempt introducer used for placement of the implant.

The Avaulta Support System will be 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 Avaulta Solo 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 arms are not covered to maximize mesh fixation immediately post implant. The primary support mechanism is the mesh beneath the collagen sheet.

The collagen sheet is pre-attached to the central soft knit section to provide a protective barrier between the polypropylene mesh and pelvic tissues. The collagen sheet is the same as the Bard CollaMend Implant and encourages fibroblast infiltration and revascularization so that the implant gradually becomes incorporated in the surrounding tissue (reference section 3.2, K052322).

The general principles of operation of the implant are the same as the predicate UGYTEX Dual Knit Mesh.

3.2 Device Design and Materials

See Exhibit 3 for graphical representations of the subject Avaulta Support System and dimensional characteristics. See the IFU in Exhibit 5 for a graphical representation of the predicate device. The subject device description follows:

Synthetic Mesh Implant

- The implant is composed of lightweight, non-absorbable, monofilament, polypropylene mesh to provide permanent, long term support.
- A knit pattern which allows the mesh to be cut in any shape without unraveling and provides multidirectional elasticity and strength.

- A design with large, open pores similar to the predicate UGYTEX Dual Knit Mesh which will allow tissue ingrowth, revascularization and cellular infiltration resulting in natural healing.
- Precut, specific geometry for anterior and posterior repair which conforms to natural vaginal length and anatomy. The precut pattern also includes an apical flap which can be used for apical support/fixation at the discretion of the physician.
- The same knit pattern is used for the anterior and posterior graft with the only difference being the width of the central section.

Synthetic Mesh Implant – Central Section
- Soft knit for compliant organ support.
- 3 mil fiber for the base mesh and a 4 mil inlay fiber for added strength.
- A blue polypropylene fiber is knit down the center as a midline marker to aid the physician in orientation and proper placement.

Synthetic Mesh Implant – Lateral Section/Arms
- Strong knit for tension free fixation of the implant.
- 4 mil fiber for the base mesh and a 4 mil inlay fiber for added strength.
- Two blue polypropylene fibers are knit in the arms on one side as a marker to aid the physician in orientation and proper placement.
- The arms are folded over on the ends to facilitate placement.

Porcine Collagen Sheet (Avaulta Plus Support System implant)
- The collagen sheet is composed of acellular, porcine dermal collagen and its constituent elastin fibers.
- The collagen is crosslinked so it resists attack and biodegradation by collagenase, allowing for a long-term, durable surgical repair.
- Lyophilized, porcine collagen sheet is mechanically attached over one side of the central soft knit section using a polypropylene fiber.
- The stitch pattern which secures the collagen to the mesh allows the physician to trim the central section without unraveling the stitch.
- 1.8 mm pores throughout the collagen which allows tissue ingrowth and macrophage penetration resulting in natural healing.

Answers to the following questions regarding the source of the collagen component are provided below as indicated in the "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," issued March 2, 1999 (answers in **bold**).

1. (b) (4)
2. (b) (4)
   a. (b) (4)
   b. (b) (4)
   c. (b) (4)

d. (b) (4)

e. (b) (4)

f. (b) (4)

3. (b) (4)

a. (b) (4)

b. (b) (4)

c. (b) (4)

3.3 Modifications Addressed in this Submission

The subject Avaulta Support System implant and predicate UGYTEX Dual Knit Mesh are of the same general design in that both are composed of low density, porous, polypropylene mesh (see Exhibit 3) which allows tissue ingrowth, revascularization and macrophage penetration. The grafts are precut in similar configurations for anterior and posterior repair and are offered with porcine collagen on the central soft mesh section. Both grafts are provided with Class I, Exempt introducers for use in placement. Both devices rely on the same fundamental scientific technology.

The primary design difference is in form of the porcine collagen placed over the center mesh. The predicate UGYTEX Dual Knit Mesh uses a clear, hydrophilic porcine collagen film whereas the subject device uses a lyophilized, crosslinked, acellular porcine collagen sheet. The collagen sheet is the same as Bard's CollaMend Implant (K052322) with some minor dimensional differences:

- The collagen sheet on the Avaulta Plus implant is 0.5mm thick while the CollaMend Implant is 1mm thick. The primary purpose of the Avaulta Plus collagen sheet is to provide a protective barrier between the mesh and the pelvic organs. It is not the primary support mechanism as with the CollaMend Implant. The support for the repair is provided by the underlying synthetic mesh.

- The Avaulta Plus collagen sheet is cut to fit the mesh implant central section and is more porous with 1.8mm diameter holes placed throughout the sheet. The CollaMend Implant is provided in various sizes and shapes without the holes.

Exhibit 6 contains a table comparing the design and materials of the predicate and subject devices.

3.4 Device Manufacturing and Marketing

The device will be manufactured by Bard Urological Division in Covington, GA and Bard Shannon, Ltd. in Humacao, Puerto Rico. The device will then be sterilized by Bard Medical Division in Covington, GA and Madison, GA. The finished device will be marketed by Bard Urological Division of Covington, GA. See section 2.2 for establishment registration numbers.

3.4.1 *Collagen Processing*

(b) (4)

- (b) (4)
- (b) (4)

(b) (4)

3.4.2 *Packaging*

The Avaulta Implant will be packaged in a thermoformed blister tray with a Tyvek® lid. The sealed tray will be placed in one of two pouches:

- The Avaulta Plus synthetic/collagen implant tray will be placed in a foil/foil pouch with a Tyvek® header (similar to CollaMend Implant). After sterilization, the pouch will be sealed below the Tyvek® header (i.e. foil to foil) which will then be 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 will be placed in Tyvek®/film pouch.

The packaged implant and separately packaged Class I, Exempt introducer will be placed in a corrugate box similar to the predicate UGYTEX Dual Knit Mesh kit.

3.4.3 *Sterilization*

The Avaulta Support System is provided sterile and is intended for single patient use only. The finished device will be sterilized via a validated ethylene oxide (EtO) sterilization cycle with an SAL (Sterility Assurance Level) of 1×10^{-6} at the C. R. Bard, Inc. facilities in Covington and Madison, Georgia or by a qualified contract sterilization organization. Validation will be performed in accordance with the ANSI / AAMI / ISO 11135 - 1994 "Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization" and the product will not be distributed prior to completion of the sterilization validation.

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.

3.4.4 *Stability*

The Avaulta Support System will initially be offered with a 1 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 which demonstrate a 1 year shelf life.

3.4.5 *Labeling*

Copies of draft, representative subject device labeling and IFU have been included in Exhibit 4 and in Exhibit 5 for the predicate device.

3.4.6 *Kit Component Certification*

Exhibit 9 contains a signed kit component certification for the introducers used in placement of the Avaulta Implants. This is the only stand alone component provided in the kits with the implant.

4.0 TESTING SUMMARY

4.1 Biocompatibility

Per ISO 10993-1, the recommended tests for the Avaluta implant, a permanent implant with tissue/bone contact are: cytoxicity, sensitization, irritation, acute systemic toxicity, implantation, chronic/subchronic toxicity, genotoxicity, carcinogenicity (if warranted by genotoxicity results).

The Avaulta implant is composed of two primary materials: dermal porcine collagen and synthetic polypropylene (a natural fiber and a blue fiber). These materials are used in other legally marketed medical devices with the same ISO 10993-1 contact profiles. All the 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
Central and lateral colored markers	Blue polypropylene monofilament fiber	**K050947** – US Surgical SurgiPro II Suture
Collagen sheet	Lyophilized, crosslinked, acellular, porcine dermal collagen	**K052322** – Bard CollaMend Implant (predicate)

To provide additional confirmation of biological acceptability, samples of the subject device underwent an additional battery of selected biological and chemical assays. Testing was performed on sterile, finished subject devices. All testing was conducted in accordance with ISO 10993. See the table below for a summary of the testing and results. Test reports can be found in Exhibit 7.

Test	Results
Gas Chromatography Mass Spectroscopy Characterization	Water: No extractable Ethanol: No extractable
USP Physicochemical	Nonvolatile residue 4.6mg – PASS Residue on Ignition < 1ppm – PASS Heavy Metals < 5mg – PASS Buffering Capacity – 0.05 ml – PASS
Sensitization – Local Lymph Node Assay	Non Sensitizing – PASS
Irritation – Vaginal Mucosal	Non irritant – PASS
Cytotoxicity – MEM Elution	Reaction Grade 0 – PASS

4.2 Collagen Testing

(b) (4)

4.2.1 *Viral Inactivation*

(b) (4)

[redacted]

4.2.2 *Chemical Residuals*

(b) (4)

[redacted]

4.2.3 *Histological Analysis*

(b) (4)

[redacted]

(b) (4)

4.2.4 *Protein, Lipid and Carbohydrate Content*

(b) (4)

4.2.5 *Collagen Typing*

(b) (4)

4.3 Design Testing and Characterization

Design testing and characterization was performed to demonstrate safety and effectiveness of the subject Avaulta Implant for its intended use. The following tests were conducted in accordance with FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 2, 1999):

- Implant thickness
- Pore size
- Density
- Tensile strength
- Device stiffness
- Suture pullout strength

- Burst strength
- Tear resistance

The central soft mesh and arm strong mesh for the Avaulta implant are the same regardless of whether the implant has been precut for posterior or anterior repair (with the exception of tensile strength which is tested in the finished anterior and posterior shapes). Consequently, all mesh only properties are measured and assessed independent of shape.

The following sections summarize the functional testing. In summary, all testing indicates the subject device is substantially equivalent to the predicate device.

4.3.1 *Implant Thickness*

Purpose
This test measures the thickness of the implant in the following locations for the subject device: mesh only in the central section, hybrid (mesh and collagen together in center section) dry and wet and the strong mesh in the arms. Thickness measurements in the predicate device are in the central section with the collagen film removed and in the arm.

Method
The thickness is measured using a thickness gauge.

Subject Device Pre-Conditioning
- 2x EtO sterilized
- 3 minute soak (hybrid only, as applicable)

Acceptance Criteria
Mesh only, center section – 0.4 ± 0.2mm
Mesh only, arm section – 0.5 ± 0.2mm
Hybrid dry, center section – 1.0 ± 0.5mm
Hybrid wet, center section – 1.0 ± 0.5mm

Results

Implant Thickness						
Units of measure – mm	Subject Device Avaulta				Predicate Device UGYTEX	
	Mesh Center	Mesh Arm	Hybrid Dry	Hybrid Wet	Center	Arm
n	30	30	180	180	30	30
Mean	0.29	0.43	0.75	0.65	0.31	0.38
Std. Dev.	0.02	0.02	0.09	0.06	0.01	0.01
Minimum	0.25	0.41	0.54	0.50	0.30	0.36
Maximum	0.35	0.48	0.99	0.77	0.33	0.39

Discussion
The data for the hybrid implant met the thickness requirement, however, it was very close to the lower end of the tolerance range. The hybrid thickness specification (dry and wet) will be revised to 0.8 ± 0.5mm to provide a more representative thickness specification of the final design which has demonstrated acceptable functional performance in design qualification testing.

Conclusions
Implant thickness met the acceptance criteria and is substantially equivalent to the predicate device. The data for the hybrid implant met the thickness requirement, however it was very close to the lower end of the tolerance range. To more accurately define hybrid thickness, the hybrid thickness for dry and wet will be revised to 0.8 ± 0.5mm.

4.3.2 *Pore Size*

Purpose
This test measures the pore size in the following locations: Central soft mesh, arm strong mesh and collagen sheet.

Method
The smallest and greatest distance across the large pores in the mesh and the diameter of the punched holes in the collagen sheet are measured using a vision system.

Subject Device Pre-Conditioning
- 2x EtO sterilized

Acceptance Criteria
Mesh pore size – > 0.5mm
Collagen sheet pore diameter – 1.8 ± 0.5mm

Results

Pore Size					
Units of measure – mm	Subject Device Avaulta			Predicate Device UGYTEX	
	Mesh Center	Mesh Arm	Collagen Sheet	Mesh Center	Mesh Arm
n	120	120	180	120	120
Mean	1.3	1.0	1.7	1.6	1.4
Std. Dev.	0.42	0.15	0.03	0.27	0.06
Minimum	0.8	0.7	1.6	1.1	1.3
Maximum	1.9	1.3	1.8	1.9	1.6

Conclusions
Pore size met the acceptance criteria and is substantially equivalent to the predicate device.

4.3.3 *Density*

Purpose
This test measures the density of the pores in the collagen sheet and the density of the synthetic mesh in the center soft knit and arm strong knit sections.

Method
The number of pores in a 1 x 1 inch section of the collagen sheet are counted and recorded. The weight of a 4 x 9 cm section of the mesh is measured and expressed as weight per unit of surface area.

Subject Device Pre-Conditioning
- 2x EtO sterilized

Acceptance Criteria
Mesh, center section – < 60 g/m^2
Mesh, arm section – < 80 g/m^2
Collagen sheet – 56 ± 15 holes per square inch

Results

Pore Density					
Units of measure – collagen: holes/inch^2 mesh: g/m^2	Subject Device Avaulta			Predicate Device UGYTEX	
	Mesh Center	Mesh Arm	Collagen Sheet	Mesh Center	Mesh Arm
n	15	30	30	10	20
Mean	33.7	64.5	55.9	33.6	69.4
Std. Dev.	0.98	1.41	0.31	0.74	0.81
Minimum	31.0	61.6	55	32.7	68.0
Maximum	34.6	68.1	56	35.0	71.1

Conclusions
Pore density meets the acceptance criteria and is substantially equivalent to the predicate device.

4.3.4 *Tensile Strength*

Purpose
This test measures the tensile strength of the implant.

Method
The precut implant is held along the midline of the central section and each arm is pulled to break. The force required to break the arm off is measured and recorded.

Subject Device Pre-Conditioning
- 2x EtO sterilized

Acceptance Criteria
Mean tensile strength equivalent to or greater than the subject UGYTEX Dual Knit Mesh with 95% confidence.

Results

Tensile Strength – Anterior, Proximal Arms			
Units of measure – lbs. force	Subject Device Avaulta		Predicate Device
	Mesh	Hybrid	UGYTEX
n	60	22	20
Mean	12.9	13.2	9.9
Std. Dev.	1.3	1.4	1.2
Minimum	9.7	10.7	7.6
Maximum	16.5	15.3	12.0

Tensile Strength – Anterior, Distal Arms			
Units of measure – lbs. force	Subject Device Avaulta		Predicate Device
	Mesh	Hybrid	UGYTEX
n	60	30	20
Mean	14.7	15.2	13.4
Std. Dev.	1.1	1.2	1.1
Minimum	12.0	12.1	11.0
Maximum	17.5	17.1	15.5

Tensile Strength – Posterior, Proximal Arms			
Units of measure – lbs. force	Subject Device Avaulta		Predicate Device
	Mesh	Hybrid	UGYTEX
n	60	30	20
Mean	15.1	14.6	6.3
Std. Dev.	1.0	0.9	0.8
Minimum	11.8	12.4	5.1
Maximum	16.9	16.5	8.0

Tensile Strength – Posterior, Distal Arms			
Units of measure – lbs. force	Subject Device Avaulta		Predicate Device
	Mesh	Hybrid	UGYTEX
n	60	30	20
Mean	7.8	9.3	4.3
Std. Dev.	0.8	1.2	0.9
Minimum	6.0	7.6	2.5
Maximum	10.2	11.7	5.8

Conclusions

The mean tensile strength of the subject Avaulta and the predicate UGYTEX Dual Knit was statistically compared using a t-test at 95% confidence. The tensile strength results met the acceptance criteria and are substantially equivalent to the predicate device.

4.3.5 *Device Stiffness*

Purpose
This test measures the stiffness of the implant in the central section and in the arms.

Method
Stiffness is measured according to ASTM D 6125-97. Measurements are taken in two orientations on the mesh alone: machine direction and cross direction. The hybrid subject device stiffness could only be measured in the machine direction and the predicate device could only be measured in the center section due to the minimum size requirements of the test equipment. To accurately perform the test on the predicate device, the collagen was removed prior to testing.

Subject Device Pre-Conditioning
- 2x EtO sterilized
- 3 minute soak (hybrid only, as applicable)

Acceptance Criteria
None – Test performed for comparison and characterization purposes only

Results

Stiffness							
Units of measure – mg	Subject Device Avaulta					Predicate Device UGYTEX	
	Mesh Center Cross	Mesh Center Machine	Mesh Arm Cross	Mesh Arm Machine	Hybrid Center Machine	Center Cross	Center Machine
n	30	30	30	30	30	10	10
Mean	30.8	63.2	68.9	165.8	329.1	39.7	54.4
Std. Dev.	2.8	5.3	6.3	23.1	56.0	4.1	2.2
Minimum	26.6	53.3	59.9	119.9	222.0	33.3	51.1
Maximum	35.5	73.3	73.3	226.4	427.0	46.6	57.7

Discussion
Stiffness of the subject "mesh center cross" and "mesh center machine" are comparable to the data of the predicate device based on the similarities in design. Measurements taken on the subject "mesh arm cross" and "mesh arm machine" do not have a comparable data set in the predicate device due to test limitations mentioned above. Subject measurements "hybrid center machine" do not have a comparable data set in the predicate device due to the addition of the collagen sheet.

Conclusions
Device stiffness is substantially equivalent to the predicate device.

4.3.6 *Suture Pullout Strength*

Purpose
This test measures the force required to pull a suture loop through the mesh.

Method
A 2-0 surgical suture is placed through the mesh 5-7mm from the edge. The ends of the suture are tied off. The suture loop is pulled through the mesh until the suture or the mesh breaks. The maximum force is recorded. The test is run in both the machine direction and cross direction.

The mesh only version of the subject device was tested to represent worst case and because the collagen is not intended to provide additional strength to the implant.

Subject Device Pre-Conditioning
- 2x EtO sterilized

Acceptance Criteria
Center section – < 0.5 lbs. force
Arm section – < 1.0 lbs. force

Results

Suture Pull Out – Center Section				
Units of measure – lbs. force	Subject Device Avaulta		Predicate Device UGYTEX	
	Cross	Machine	Cross	Machine
n	30	30	10	10
Mean	3.2	3.6	3.9	4.1
Std. Dev.	0.64	0.41	0.43	0.46
Minimum	1.9	2.6	3.4	3.4
Maximum	4.5	4.2	4.8	4.7

Suture Pull Out – Arm Section				
Units of measure – lbs. force	Subject Device Avaulta		Predicate Device UGYTEX	
	Cross	Machine	Cross	Machine
n	30	30	10	10
Mean	5.7	5.3	7.2	6.6
Std. Dev.	0.60	0.67	0.79	1.00
Minimum	4.7	4.1	6.3	4.8
Maximum	7.1	6.6	8.4	7.9

Conclusions
Each data set met the acceptance criteria and is substantially equivalent to the predicate device.

4.3.7 *Burst Strength*

Purpose
This test measures the force required to push a ball through the implant.

Method
Ball burst strength is measured according to ASTM D 3787-89. The steel ball used was 3/8 inch in diameter to facilitate testing of smaller samples.

The mesh only version of the subject device was tested to represent worst case and because the collagen is not intended to provide additional strength to the implant. Only the central section of the predicate device was tested due to the minimum size requirements of the test equipment.

Subject Device Pre-Conditioning
- 2x EtO sterilized

Acceptance Criteria
Center section – < 5 lbs. force
Arm section – < 10 lbs. force

Results

Burst Strength			
Units of measure – lbs. force	Subject Device Avaulta		Predicate Device UGYTEX
	Mesh Center	Mesh Arm	Mesh Center
n	30	30	10
Mean	20.9	32.3	28.6
Std. Dev.	2.8	3.2	2.1
Minimum	16.0	22.7	24.5
Maximum	25.6	38.7	31.4

Conclusions
Burst strength meets the acceptance criteria and is substantially equivalent to the predicate device.

4.3.8 *Tear Resistance Test*

Purpose
This test measures the force to tear the implant.

Method
Tear resistance is measured according to ISO 4674-1977 in both machine direction and cross directions to characterize mesh properties.

The central soft knit mesh only version of the subject device was tested to represent worst case. The predicate could not be tested due to the minimum size requirements of the test i.e. the predicate device in its finished form is not large enough.

Subject Device Pre-Conditioning
- 2x EtO sterilized

Acceptance Criteria
None – Results are for characterization only

Results

Tear Resistance		
Units of measure – lbs. force	Subject Device Avaulta	
	Cross	Machine
n	30	20
Mean	5.5	5.1
Std. Dev.	1.00	0.48
Minimum	4.0	4.5
Maximum	7.5	6.1

Discussion
A direct comparison to tear resistance of the predicate device could not be made because the predicate did not meet the minimum size requirements of the test. However, the predicate tensile strength shows a worst case average strength as low as 4.3 lbs. force (see section 4.3.4). Furthermore, all other functional subject device characteristics showed acceptable results and compared favorably to the predicate device.

Conclusions
The subject Avaulta Implant is functionally comparable to the predicate UGYTEX Dual Knit Mesh.

5.0 SUBSTANTIAL EQUIVALENCE

BUD intends to introduce the Avaulta Support System which is substantially equivalent to the predicate UGYTEX Dual Knit Mesh (K051503) and the CollaMend Implant (K052322).

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 8. 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 the subject Avaulta Support System is the same as the predicate UGYTEX Dual Knit Mesh. Both devices are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse.

2. **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 device uses a porcine collagen sheet vs. the collagen film on the predicate UGYTEX Dual Knit Mesh. However, the collagen sheet is the same as the CollaMend Implant with the exception of thickness and porosity.

3. **Could the new characteristics affect safety or effectiveness?**

   Yes. A change in materials could affect safety and effectiveness.

4. **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. The subject device is roughly a combination of the two predicate devices which does not raise new types of safety and effectiveness questions.

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

   Yes. Biocompatibility has been addressed through adherence to ISO 10993. Functional performance has been addressed by conducting testing

as recommended by FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."

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

Yes. Biocompatibility and functional performance data are included herein. The collagen sheet has been fully tested in K052322 and the results have been reviewed and determined to provide sufficient data supporting the use of the thinner collagen sheet in the Avaulta Implant.

7. Performance data demonstrate equivalence?

Yes. The data contained herein demonstrate equivalence.

Based on the answers to the above questions, the subject Avaulta Support System is substantially equivalent to the predicate UGYTEX Dual Knit Mesh (K051503) and the CollaMend Implant (K052322).

Exhibit 1

Premarket Notification [510(k)] Checklist for Acceptance Decision and Required Information

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PREMARKET NOTIFICATION [510(K)] CHECKLIST FOR ACCEPTANCE DECISION AND REQUIRED INFORMATION

The following checklist is taken from CDRH's Premarket Notification [510(k)] Refuse to Accept Policy. An explanation for the omission of any item on the checklist will be provided.

I. **CRITICAL ELEMENTS:**
The Avaulta Support System is a device, as defined in Sec. 201 of the Federal Food, Drug, and Cosmetic Act, as Amended (the Act), which is not exempt from the 510(k) requirements, by regulation or by policy, and is subject to review by CDRH.

a. Has the device been the subject of a previous NSE decision? **NO**

II. **REQUIRED INFORMATION (under Sections 510(k), 513(f), and 512(l) of the Act, and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations):**

Description	Location
a. Device trade or proprietary name:	Section 2.2
b. Device common or usual name, or classification name:	Section 2.2
c. Establishment registration number: Owner/Operator#:	Section 2.2
d. Class into which the device is classified under (21 CFR Parts 862 to 892):	Section 2.2
e. Classification panel:	Section 2.2
f. Action taken to comply with Section 514 of the Act:	Section 2.2
g. Proposed labels, labeling instructions for use, and advertisements (if available) that describe the device, its intended use, and directions for use:	Section 3.4.5 Exhibit 4
h. 510(k) Safety and Effectiveness Information	Exhibit 2
i. For class III devices only, a class III certification and a class III summary:	Not Applicable – Class II device
j. Photographs of the device:	See Exhibit 3 for graphical representation.
k. Engineering drawings for the device with dimensions and tolerances:	See Exhibit 3
l. The marketed device(s) to which equivalence is claimed including labeling and description of the device:	Section 2.2 and Exhibit 5

Description	Location
m. Statement of similarities and/or differences with the marketed device(s):	Section 3.0
n. Data to show consequences and effects of a modified device:	Section 4.0

III. **ADDITIONAL INFORMATION that is necessary under 21 CFR 807.87(h):**

Description	Location
a. Submitter's name and address:	Section 2.2
b. Contact person, telephone number and fax number	Section 2.2
c. Representative/Consultant, if applicable:	Not Applicable
d. Table of contents with pagination:	Table of Contents
e. Manufacturing facility/facilities name and address:	Section 1.1 and Section 2.2
f. Sterilization site(s) name and address	Section 1.1 and Section 2.2

IV. **ADDITIONAL INFORMATION that may be necessary under 21 CFR 807.87(h):**

Description	Location
a. Comparison table of the new device to the marketed device(s):	Exhibit 6
b. Action taken to comply with voluntary standards:	Section 2.2
c. Performance data:	
Marketed device	
Bench testing	Section 4.3
Animal testing	Not Applicable. Bench testing is adequate to establish substantial equivalence.
Clinical testing	Not Applicable. Bench testing is adequate to establish substantial equivalence.
New device	
Bench testing	See Section 4.0
Animal testing	Not Applicable. Bench testing is adequate to establish substantial equivalence.
Clinical testing	Not Applicable. Bench testing is adequate to establish substantial equivalence.

	Description	Location
d.	Sterilization information:	Section 3.4.3
e.	Software information:	Not applicable. The device has no software.
f.	Hardware information:	Not applicable. Not a feature of this device.
g.	Is the device subject to issues that have been addressed in specific guidance documents?	No

Exhibit 2

510(k) Summary of Safety and Effectiveness

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

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 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

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).

Exhibit 3

Subject Device Drawings and Photos

ANTERIOR PRE-CUT CONFIGURATION

Figure 1: Dimensions

Figure 2: Avaulta Solo Synthetic Support System

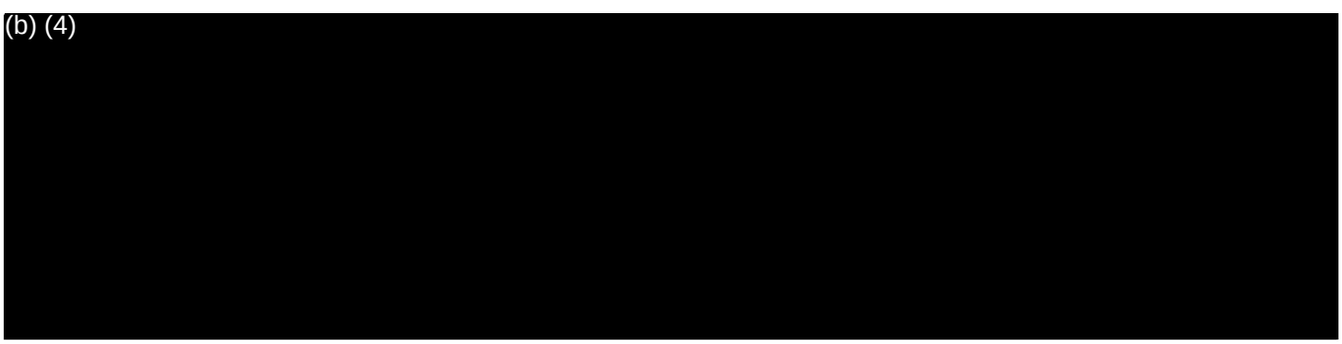


Figure 3: Avaulta Biosynthetic Support System

POSTERIOR PRE-CUT CONFIGURATION

Figure 4: Dimensions

Figure 5: Avaulta Solo Synthetic Support System

Figure 6: Avaulta Plus Biosynthetic Support System

Figure 7: Avaulta Central Soft Mesh

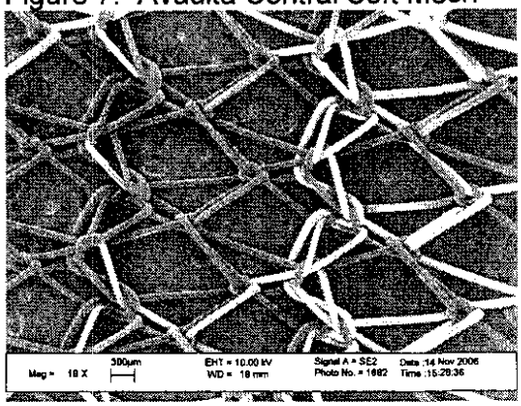


Figure 8: Avaulta Arm Strong Mesh

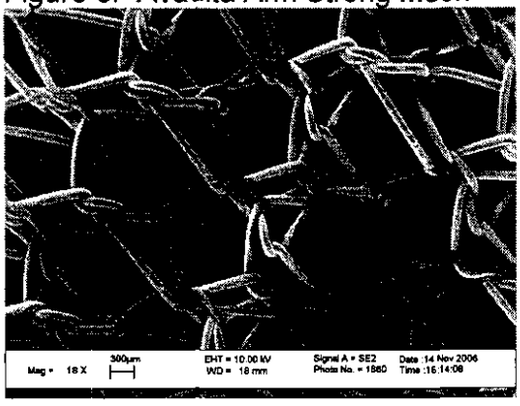


Figure 9: UGYTEX Central Soft Mesh

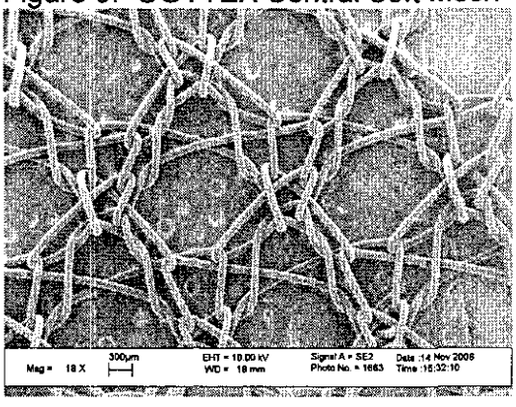


Figure 10: UGYTEX Arm Strong Mesh

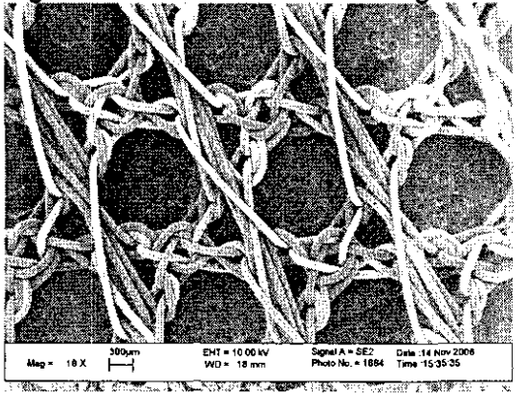


Exhibit 4

Subject Device Labeling

- Instructions for Use
- Labels

DRAFT

Avaulta Plus™ Biosynthetic Support System and Avaulta Solo™ Support System

Instructions for Use

DESCRIPTION
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 the ingrowth of host tissue and capillary vessels.

The monofilament, polypropylene mesh used in both the Avaulta Plus™ Biosynthetic Support System and Avaulta Solo™ Support System has a soft knit in the central section for compliant organ support and host tissue ingrowth, and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open knit design offers multidirectional strength and elasticity that allows the synthetic mesh to be trimmed at the physician's discretion without unraveling and to adapt to various body stresses.

The pre-attached collagen sheet on the Avaulta Plus™ Biosynthetic Support System covers the soft-knit central section of the mesh to provide both a thin collagen plane for ingrowth of native tissue as well as a protective mucosal tissue barrier. The lateral segments of the Avaulta Plus™ Biosynthetic Support System are not covered to maximize mesh fixation immediately post-implantation.

As a convenience to the physician, both the Avaulta Plus™ Biosynthetic Support System and the Avaulta Solo™ Support System consist of a pre-cut graft for vaginal wall prolapse repair and an introducer needle to help facilitate placement of the graft. The graft may be further trimmed by the physician to achieve the desired geometry for the procedure.

The instrumentation included in both the Avaulta Plus™ Biosynthetic Support System and the Avaulta Solo™ Support System features a unique, patent-pending flexible snare system designed to minimize tissue trauma during implantation and allow for easier tip exteriorization and mesh arm capture.

INDICATIONS
Avaulta Plus™ Biosynthetic Support System and Avaulta Solo™ Support System are 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.

CONTRAINDICATIONS
Avaulta Plus™ Biosynthetic Biosynthetic Support System and Avaulta Solo™ Support System are contraindicated for patients who are pregnant or may become pregnant, have a urinary tract infection, have an infection in the operative field, or patients in a period of growth because the mesh may not stretch significantly.

Avaulta Plus™ Biosynthetic Support System with acellular dermal tissue has material derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

ADVERSE REACTIONS
Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, mucosal or visceral erosion, infection, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum, or any viscera may occur during needle passage.

PRECAUTIONS
- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Avaulta Plus™ Biosynthetic Support System and Avaulta Solo™ Support System should only be used by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction and the implantation of nonabsorbable meshes.

- Acceptable surgical practices should be followed for the management of infected or contaminated wounds.
- The Avaulta Plus™ Biosynthetic Support System and Avaulta Solo™ Support System implantation procedures require diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- Avaulta Plus™ Biosynthetic Support System and Avaulta Solo™ Support System are provided in a sterile blister tray within a sterile pouch. The sterile blister tray may be placed in the sterile field.
- The introducers provided with the Anterior and Posterior Support Systems are provided in a sterile blister tray. Transfer the introducer to the sterile field using aseptic techniques. Do not place the tray in the sterile field.
- Check the integrity of the packaging before use. Do not use the mesh or introducers if the packaging is opened or damaged.
- As for any implantable material, it is recommended to open the blister tray at the time of implantation.
- After use, any unused product and packaging should be treated as a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

IMPLANT PROCEDURES

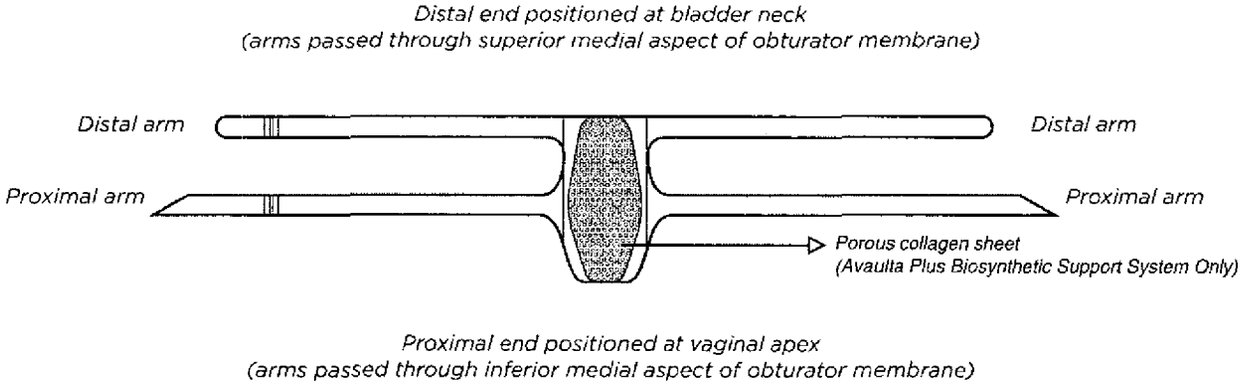
Preparation of Avaulta Plus™ Biosynthetic mesh for Implantation:

At the time of implantation, Avaulta Plus™ Biosynthetic Support System mesh must be hydrated. To hydrate, place the Avaulta Plus™ Biosynthetic Support System mesh into the blister tray or other sterile dish and completely immerse in a sterile physiological solution for at least 3 minutes.

Avaulta Plus™ Biosynthetic Support System mesh is more easily trimmed prior to hydration, but may be trimmed after hydration if desired.

CAUTION: The mesh should not be trimmed to a width less than 1 cm in order to maintain sufficient strength and prevent unraveling.

Implantation Technique for the Avaulta Plus™ Biosynthetic Anterior Support System and the Avaulta Solo™ Anterior Support System:



- Note: When using the Avaulta Plus™ Biosynthetic Support System, the tissue layer of the graft may be oriented to face the vaginal mucosal tissue or the visceral side at the discretion of the physician. To help facilitate the desired orientation, the colored markers on the arms should be positioned on the patient's right side for the tissue layer to be positioned on the vaginal mucosal side. Conversely, the arm markers should be oriented on the patient's left side for the tissue layer to face the visceral side.
- Note: The Avaulta Solo™ Support System does not require a particular orientation with respect to mucosal or visceral sidedness.
- Proximal end with apical flap positioned at vaginal apex
- Proximal arms (long arms with pointed ends) passed through inferior medial aspect of obturator membrane
- Distal end positioned at bladder neck
- Distal arms (short arms with rounded ends) passed through superior medial aspect of obturator membrane

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1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.

2. Make a midline incision in the anterior vaginal wall starting 1 cm below the urethral meatus and extending to the vaginal cuff. Dissect the vaginal mucosa away from the bladder laterally to the obturator internus at the level of the bladder neck and proximally to the ischial spine on both sides.

3. Identify the obturator fossa by grasping the adductor longus at its insertion to the pubic tubercle. Using the thumb to palpate under the adductor longus insertion, the superior medial aspect of the obturator fossa is identified. Palpate and draw the medial border of the obturator fossa to its inferior medial border. Make a vertical 1.5 cm incision approximately 1 cm below the superior medial border of the obturator fossa and lateral to the bladder neck for the distal arm of the mesh. Make a second vertical 1.5 cm incision at the inferior medial border of the obturator fossa and approximately lateral to the vaginal cuff. Repeat on the contralateral side.

4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the inferior medial groin incision to puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle tip towards the ischial spine or top of the vaginal cuff. Identify the tip of the introducer before puncturing through the obturator internus muscle. With a gentle rotation of the introducer push through the obturator muscle and use the vaginal finger to guide the needle tip through the fascial wall to exit proximally at the vaginal apex, exposing at least 1-2 cm of the needle tip. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself.

5. Pass the proximal arm (pointed end) of the mesh up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the inferior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.

6. Apply traction to draw the proximal (inferior) arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Be sure the graft is tension-free.

7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the superior groin incision and gently puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle towards the level of the bladder neck. Use a vaginal finger to guide the needle tip through the obturator internus as before, exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.

8. Pass a distal arm (rounded end) of the mesh up to the fold (about 4 cm) through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the superior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.

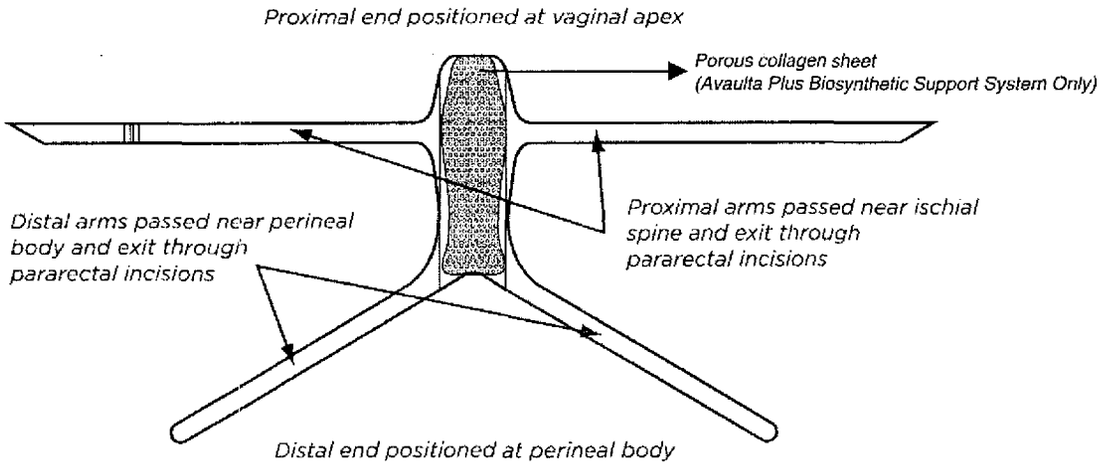
9. Apply traction to draw the distal (superior) arms of the graft into the desired position such that the distal end of the central graft is positioned near the bladder neck. If significant folds are observed, scissors may be used to cut a small section out of the midline of the graft under the bladder neck. Apply additional traction to the distal (superior) arms to help take up the slack and flatten the mesh under the bladder. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central graft is positioned under the bladder without excessive tension. A cystoscopy should be performed to confirm integrity of the bladder after the mesh has been positioned.

10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. Extra care should be used when positioning the Avaulta Plus™ Biosynthetic Support System implant to prevent tearing of the acellular collagen sheet. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.

    Caution: Excessive tension should be avoided on the mesh suture attachment points to account for wound shrinkage during the healing process.

11. Close the anterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

Implantation Technique for the Avaulta™ Posterior Support System:



- Note: When using the Avaulta Plus™ Biosynthetic Support System, the tissue layer of the graft may be oriented to face the vaginal mucosal tissue or the visceral side at the discretion of the physician. To help facilitate the desired orientation, the colored markers on the arms should be positioned on the patient's right side for the tissue layer to be positioned on the vaginal mucosal side. Conversely, the arm markers should be oriented on the patient's left side for the tissue layer to face the visceral side.
- Note: The Avaulta Solo™ Support System does not require a particular orientation with respect to mucosal or visceral sidedness.
- Proximal end with apical flap positioned at vaginal apex
- Proximal arms (long arms with pointed ends) passed through ischiorectal fossa
- Distal end positioned at perineal body
- Distal arms (short arms with rounded ends) passed through ischiorectal fossa

1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.

2. Make a midline incision in the posterior vaginal wall starting at the vaginal introitus and extending to the vaginal apex. Starting at the perineal body, use blunt and sharp dissection to dissect the vaginal mucosa away from the rectum laterally to the pelvic sidewalls and proximally to the ischial spine on both sides.

3. Make two small pararectal incisions (1-2 cm) approximately 3 cm lateral and 3 cm posterior to the anus.

4. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Orient the introducer needle with the handle positioned vertically and the needle tip horizontal and parallel to the vaginal floor. Insert the needle tip into one of the pararectal incisions, aiming the needle tip towards the ischial spine. Pass the introducer through the ischiorectal fossa passing lateral to the posterior wall of the rectum until the needle tip nears the ischial spine. Move the handle downwards to direct the needle tip upwards approximately 1 cm proximal to the ischial spine and out through the posterior vaginal wall incision, exposing at least 1-2 cm of the needle tip. At the physician's discretion, the proximal arms may be secured through the sacrospinous ligament using a similar motion. Exercise care not to tear the pelvic tissue during passage. Insert a right-angle retractor into the vagina along the anterior wall and extend the introducer snare using the thumb slider on the introducer handle. The introducer tip should be stabilized with two fingers during initial deployment of the snare. If necessary, guide the end of the snare to the introitus with a finger. Extend the thumb slider until the snare loop has fully exteriorized itself. *Note: It is recommended that a rectal probe be used to divert the rectum away during the needle passage.*

5. Pass the proximal mesh arm (pointed end) up to the fold (about 5 cm) through the eyelet in the snare. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.

6. Apply traction to draw the proximal arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Avoid placing excessive tension on the graft.

7. Locate the introducer needle and ensure that the snare is fully retracted into the needle tip prior to inserting the needle. Insert the tip of the introducer needle into the same pararectal incision created in Step 3 and orient the needle tip towards the vaginal introitus. Exercise care to stay lateral to the anal sphincter and rectum during passage. Use a vaginal finger to guide the needle tip through the posterior vaginal wall incision at the perineal body, exposing at least 1-2 cm of the needle tip. Extend the introducer snare using the thumb slider on the introducer handle until the snare loop has fully exteriorized itself at the vaginal introitus.

8. Pass the distal mesh arm (rounded end) 3-4 cm through the eyelet in the needle tip. Retract the snare using the thumb slider until it reaches the stop position. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.

9. Apply traction to draw the distal arms of the graft into the desired position such that the distal end of the central graft is positioned next to the perineal body. Use scissors to make a small midline cut in the central graft to approximate the length from the vaginal apex to the perineal body. Apply additional traction to the distal arms to position the central mesh as desired. The colored midline marker may be used to facilitate desired placement of the graft. Ensure the central graft is positioned under the bladder without excessive tension. Ensure the central mesh lays over the rectum without excessive tension. A digital rectal exam should be performed to confirm integrity of the rectum after the mesh is positioned.

10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. Extra care should be used when positioning the Avaulta Plus™ Biosynthetic Support System implant to prevent tearing of the acellular collagen sheet. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.

    Caution: Excessive tension should be avoided on the mesh suture attachment points to account for wound shrinkage during the healing process.

11. Close the posterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

DRAFT

STERILIZATION TECHNIQUE
Avaulta Plus™ Biosynthetic Support System and Avaulta Solo™ Support System are single-use devices. The implant and introducers are sterilized by ethylene oxide. Do not resterilize.

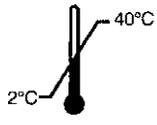
STORAGE
Recommended storage conditions: between 2°-40°C (36°-105°F) in a dry area.


Read instructions for use


Single Use


Do not resterilize

STERILE EO
Sterilized using Ethylene Oxide



Temperature Limitation

LOT
Lot number

EC REP
Authorized Representative


Sterile unless package is opened or damaged.


Manufacturer

Rx Only
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.


Use By

REF
Catalog Number


Date of Manufacture

BARD

C. R. Bard, Inc.
Covington, GA 30014
1-888-367-2273
www.bardurological.com

PK0301743 10/06

DRAFT

KIT BOX

81

BRAFT

BARD

C. R. Bard, Inc.
Covington, GA 30014, U.S.A.
1.888.367.2273
www.bardurological.com

EC REP Bard Limited, Forest House
Tilgate Forest Business Park
Brighton Road
Crawley, West Sussex
RH11 9BP UK
0044 1293 527 888

PK0301752 10/06

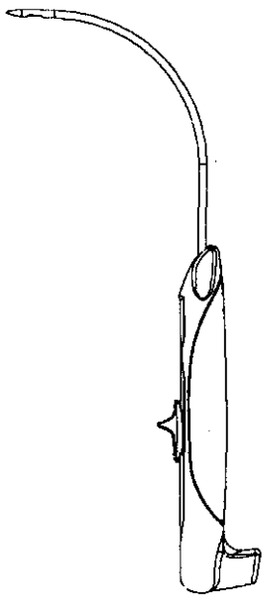
℞ only

SINGLE USE

STERILE

STERILE EO

40°C
2°C



REF: XXXXXX

LOT XXXXXX

XXXX-XX

+H301145FS80.

+H301145FS80.

E-1450-00 : 2005-05-20

87

KIT BOX LABEL

IMPLANT TRAY LABEL

DRAFT

Avaulta™ Plus

BIOSYNTHETIC SUPPORT SYSTEM

BARD
C. R. Bard, Inc.
Covington, GA 30014, U.S.A.
1.888.367.2273
www.bardurological.com

EC REP Bard Limited, Forest House
Tilgate Forest Business Park
Brighton Road
Crawley, West Sussex
RH11 9BP UK
0044 1293 527 88

PK0301754 10/06

Rx only

SINGLE USE

STERILE EO

40°C
2°C

LOT XXXXX-X

XX-XXXX

83

IMPLANT POUCH LABEL

DRAFT

Avaulta™ Plus

BIOSYNTHETIC SUPPORT SYSTEM

Posterior

BARD
AVAULTA™ PLUS BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX XXXX-XX
REF XXXXXXXX XXXX-XX

BARD
AVAULTA™ PLUS BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX XXXX-XX
REF XXXXXXXX XXXX-XX

BARD
AVAULTA™ PLUS BIOSYNTHETIC SUPPORT SYSTEM
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AVAULTA™ PLUS BIOSYNTHETIC SUPPORT SYSTEM
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AVAULTA™ PLUS BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX XXXX-XX
REF XXXXXXXX XXXX-XX

BARD
AVAULTA™ PLUS BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX XXXX-XX
REF XXXXXXXX XXXX-XX

BARD
C. R. Bard, Inc.
Covington, GA 30014, U.S.A.
1.888.367.2273
www.bardurological.com

Rx only

SINGLE USE

EC REP Bard Limited, Forest House
Tilgate Forest Business park
Brighton Road
Crawley, West Sussex
RH11 9BP UK
0044 1293 527 888

40°C
2°C

STERILE EO

PKO301747 10/06 Rev/0

®TM Bard is a registered trademark of C. R. Bard, Inc. or an affiliate.
Avaulta is a trademark of C. R. Bard, Inc. or an affiliate.

XX-XXXX

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Exhibit 5

Predicate Device Labeling

- Instructions for Use
- Labels

Note that the UGYTEX Dual Knit Mesh is currently marketed as Avaulta Biosynthetic Mesh.

Avaulta™

BIOSYNTHETIC SUPPORT SYSTEM

P-238-01
2005-08-10

GB US **AVAULTA™ ANTERIOR BIOSYNTHETIC SUPPORT SYSTEM**
AVAULTA™ POSTERIOR BIOSYNTHETIC SUPPORT SYSTEM
INSTRUCTIONS FOR USE

F **SYSTÈME DE SUPPORT ANTÉRIEUR BIOSYNTHÉTIQUE**
SYSTÈME DE SUPPORT POSTÉRIEUR BIOSYNTHÉTIQUE
NOTICE D'INSTRUCTIONS

D **AVAULTA™ ANTERIORES BIOSYNTHETIC SUPPORT-SYSTEM**
AVAULTA™ POSTERIORES BIOSYNTHETIC SUPPORT-SYSTEM
GEBRAUCHSANLEITUNG

I **AVAULTA™ SISTEMA BIOSINTETICO DI SUPPORTO ANTERIORE**
AVAULTA™ SISTEMA BIOSINTETICO DI SUPPORTO POSTERIORE
ISTRUZIONI PER L'USO

E **SISTEMA DE SOPORTE BIOSINTÉTICO ANTERIOR AVAULTA™**
SISTEMA DE SOPORTE BIOSINTÉTICO POSTERIOR AVAULTA™
INSTRUCCIONES DE USO

NL **AVAULTA™ ANTERIEUR BIOSYNTHETISCH ONDERSTEUNINGSSYSTEEM**
AVAULTA™ POSTERIEUR BIOSYNTHETISCH ONDERSTEUNINGSSYSTEEM
GEBRUIKSAANWIJZING

P **SISTEMA DE SUPORTE BIOSSINTÉTICO ANTERIOR AVAULTA™**
SISTEMA DE SUPORTE BIOSSINTÉTICO POSTERIOR AVAULTA™
INSTRUÇÕES DE UTILIZAÇÃO

GR **ΠΡΌΣΘΙΟ ΒΙΟΣΥΝΘΕΤΙΚΌ ΣΎΣΤΗΜΑ ΥΠΟΣΤΉΡΙΞΗΣ AVAULTA™**
ΟΠΊΣΘΙΟ ΒΙΟΣΥΝΘΕΤΙΚΌ ΣΎΣΤΗΜΑ ΥΠΟΣΤΉΡΙΞΗΣ AVAULTA™
ΟΔΗΓΊΕΣ ΧΡΉΣΗΣ

DK **AVAULTA™ FORRESTE BIOSYNTETISKE SUPPORTSYSTEM**
AVAULTA™ BAGERSTE BIOSYNTETISKE SUPPORTSYSTEM
INDIKATIONER FOR ANVENDELSE

SOFRADIM PRODUCTION
116, avenue du Formans
01600 Trévoux . FRANCE
Tel. +33 4 74 08 90 00
Fax +33 4 74 08 90 01

CE 0459

86

ENGLISH/US

DESCRIPTION

Avaulta™ BioSynthetic Mesh is a monofilament, polypropylene mesh coated with an absorbable, hydrophilic film of porcine collagen. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. The hydrophilic film minimizes visceral attachment to the mesh which may occur during the healing process.

Avaulta™ BioSynthetic Mesh has a soft knit in the central section for compliant organ support and a strong knit in the lateral sides to provide improved strength for tension-free fixation of the mesh. The open weave design offers multidirectional elasticity that allows the Avaulta™ BioSynthetic Mesh to be cut into any desired shape or size without unraveling and to adapt to various body stresses. The Avaulta™ BioSynthetic Mesh also has an absorbable, hydrophilic film of porcine collagen that covers the soft-knit central section of the mesh to minimize visceral attachments in this area. The lateral segments of the Avaulta™ BioSynthetic Mesh are not coated to maximize mesh fixation immediately post-implantation.

As a convenience to the physician, the Avaulta™ Anterior BioSynthetic Support System consists of a pre-cut Avaulta™ BioSynthetic Mesh graft for anterior vaginal wall prolapse repair and an introducer needle to help facilitate placement of the graft. The graft may be further trimmed by the physician to achieve the desired geometry for the procedure.

As a convenience to the physician, the Avaulta™ Posterior BioSynthetic Support System consists of a pre-cut Avaulta™ BioSynthetic Mesh graft for posterior vaginal wall prolapse repair and an introducer needle to help facilitate placement of the graft. The graft may be further trimmed by the physician to achieve the desired geometry for the procedure.

INDICATIONS

Avaulta™ BioSynthetic Mesh 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.

CONTRAINDICATIONS

Avaulta™ BioSynthetic Mesh is contraindicated for patients who are pregnant or may become pregnant, have a urinary tract infection, have an infection in the operative field, or patients in a period of growth because the mesh may not stretch significantly.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, mucosal or visceral erosion, infection, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum, or any viscera may occur during needle passage.

PRECAUTIONS

- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Avaulta™ BioSynthetic Mesh should only be used by physicians who are trained in the surgical procedures and techniques required for pelvic floor reconstruction and the implantation of nonabsorbable meshes.
- Acceptable surgical practices should be followed for the management of infected or contaminated wounds.
- The Avaulta™ BioSynthetic Mesh implantation procedure requires diligent attention to anatomical structure and care to avoid puncture of large vessels, nerves, bladder, bowel, rectum, or other viscera during needle passage.
- Excessive tension should be avoided on the Avaulta™ BioSynthetic Mesh and suture attachment points to account for wound shrinkage during the healing process.
- Avaulta™ BioSynthetic Mesh is provided in a sterile blister tray within a double-pouched package. Do not place either pouch in the sterile field. The sterile blister tray may be placed in the sterile field.
- The introducers provided with the Avaulta™ Anterior and Posterior BioSynthetic Support Systems are provided in a double-packaged tray. Do not place the outer tray in the sterile field. The inner tray is sterile and may be placed in the sterile field.
- Check the integrity of the packaging before use. Do not use the mesh or introducers if the packaging is opened or damaged.
- As for any implantable material, it is recommended to open the blister tray at the time of implantation.

IMPLANT PROCEDURES

Preparation of the Avaulta™ BioSynthetic Mesh for Implantation:

At the time of implantation, Avaulta™ BioSynthetic Mesh must be hydrated. To hydrate, place the Avaulta™ BioSynthetic Mesh into the blister tray or other sterile dish and completely immerse in a sterile physiological solution for approximately 30 seconds or until the mesh recovers its conformability and flexibility. Avaulta™ BioSynthetic Mesh is more easily trimmed prior to hydration, but may be trimmed after hydration if desired.

CAUTION: The mesh should not be trimmed to a width less than 1 cm in order to maintain sufficient strength and prevent unraveling.

Implantation Technique for the Avaulta™ Anterior BioSynthetic Support System:

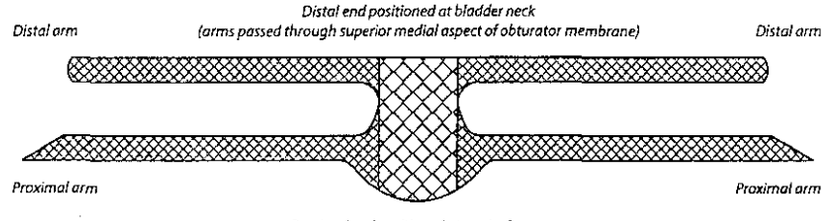

FIGURE 1. *Example of a Pre-Cut Avaulta™ BioSynthetic Mesh Anterior Graft*

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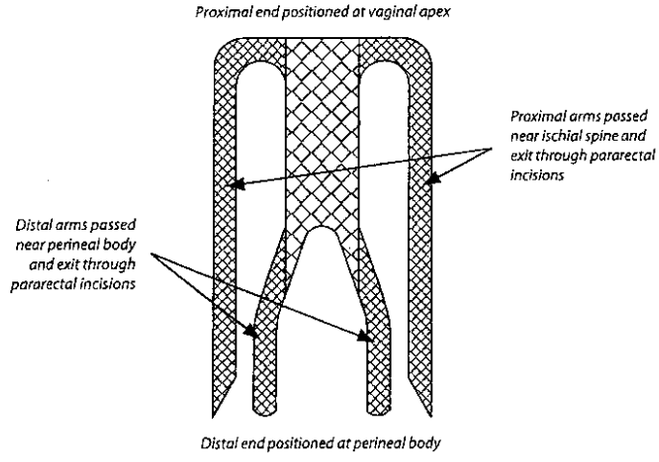
1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
2. Make a midline incision in the anterior vaginal wall starting 1 cm below the urethral meatus and extending to the vaginal cuff. Dissect the vaginal mucosa away from the bladder laterally to the obturator internus at the level of the bladder neck and proximally to the ischial spine on both sides.
3. Identify the obturator fossa by grasping the adductor longus at its insertion to the pubic tubercle. Using the thumb to palpate under the adductor longus insertion, the superior medial aspect of the obturator fossa is identified. Palpate and draw the medial border of the obturator fossa to its inferior medial border. Make a vertical 1.5 cm incision approximately 1 cm below the superior medial border of the obturator fossa and lateral to the bladder neck for the distal arm of the mesh. Make a second vertical 1.5 cm incision at the inferior medial border of the obturator fossa and approximately lateral to the vaginal cuff. Repeat on the contralateral side.
4. Insert the tip of the anterior introducer into the inferior medial groin incision to puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle tip towards the ischial spine or top of the vaginal cuff. Identify the tip of the introducer before puncturing through the obturator internus muscle. With a gentle rotation of the introducer push through the obturator muscle and use the vaginal finger to guide the needle tip through the fascial wall to exit proximally at the vaginal apex. Continue pivoting the introducer to exteriorize the needle tip at the vaginal introitus.
5. Pass the proximal arm (pointed end) of the mesh 3-4 cm through the eyelet in the needle tip. Retract the introducer needle to draw the mesh arm out through the inferior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.
6. Apply traction to draw the proximal (inferior) arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Be sure the graft is tension-free.
7. Insert the tip of the anterior introducer into the superior groin incision and gently puncture through the obturator membrane. Orient the introducer in a horizontal plane, and direct the needle towards the level of the bladder neck. Use a vaginal finger to guide the needle tip through the obturator internus as before, and then exteriorize the tip at the vaginal introitus.
8. Pass a distal arm (rounded end) of the mesh 3-4 cm through the eyelet in the needle tip. Retract the introducer needle to draw the mesh arm out through the superior groin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
9. Apply traction to draw the distal (superior) arms of the graft into the desired position such that the distal end of the central graft is positioned near the bladder neck. If significant folds are observed, scissors may be used to cut a small section out of the midline of the graft under the bladder neck. Apply additional traction to the distal (superior) arms to help take up the slack and flatten the mesh under the bladder. Ensure the central graft is positioned under the bladder without excessive tension. A cystoscopy should be performed to confirm integrity of the bladder after the mesh has been positioned.
10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.
11. Close the anterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

<u>Implantation Technique for the Avaulta™ Posterior BioSynthetic Support System:</u>



<u>FIGURE 2</u>. Example of a Pre-Cut Avaulta™ BioSynthetic Mesh Posterior Graft

1. Place the patient in stirrups in the lithotomy position and prepare for surgery using standard operative procedures.
2. Make a midline incision in the posterior vaginal wall starting at the vaginal introitus and extending to the vaginal apex. Starting at the perineal body, use blunt and sharp dissection to dissect the vaginal mucosa away from the rectum laterally to the pelvic sidewalls and proximally to the ischial spine on both sides.
3. Make two small pararectal incisions (1-2 cm) approximately 2-3 cm lateral and 2-3 cm posterior to the anus.
4. Orient the posterior introducer with the handle positioned vertically and the needle tip horizontal and parallel to the vaginal floor. Insert the needle tip into one of the pararectal incisions, aiming the needle tip towards the ischial spine. Pass the introducer through the ischiorectal fossa passing lateral to the posterior wall of the rectum until the needle tip nears the ischial spine. Move the handle downwards to direct the needle tip upwards approximately 1-2 cm proximal to the ischial spine and out through the posterior vaginal wall incision (use a vaginal finger to help guide the needle tip during passage). Continue moving the introducer handle downwards to direct the needle tip towards the vaginal introitus. Use a vaginal finger to

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help guide and exteriorize the needle tip. Exercise care not to tear the pelvic tissue during passage. Note: It is recommended that a rectal probe be used to divert the rectum away during the needle passage.

5. Pass the proximal mesh arm (pointed end) 3-4 cm through the eyelet in the needle tip. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision . Ensure the mesh arm is not twisted during or after placement. Repeat steps 4 and 5 on the contralateral side.
6. Apply traction to draw the proximal arms of the graft into the desired position such that the proximal end of the central graft is positioned at the vaginal apex. Avoid placing excessive tension on the graft.
7. Insert the tip of the posterior introducer into the same pararectal incision created in Step 3 and orient the needle tip towards the vaginal introitus. Exercise care to stay lateral to the anal sphincter and rectum during passage. Use a vaginal finger to guide the needle tip through the posterior vaginal wall incision at the perineal body, and exteriorize the tip at the vaginal introitus.
8. Pass the distal mesh arm (rounded end) 3-4 cm through the eyelet in the needle tip. Retract the introducer needle to draw the mesh arm out through the pararectal skin incision. Ensure the mesh arm is not twisted during or after placement. Repeat steps 7 and 8 on the contralateral side.
9. Apply traction to draw the distal arms of the graft into the desired position such that the distal end of the central graft is positioned next to the perineal body. Use scissors to make a small midline cut in the central graft to approximate the length from the vaginal apex to the perineal body. Apply additional traction to the distal arms to position the central mesh as desired. Ensure the central mesh lays flat over the rectum without excessive tension. A digital rectal exam should be performed to confirm integrity of the rectum after the mesh is positioned.
10. The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 cm from the edge of the mesh. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions.
11. Close the posterior vaginal wall incision using a running stitch. It is not advised to use an interrupted or locking stitch as they may cause excessive hemostasis, resulting in delayed closure.

STERILIZATION TECHNIQUE

Avaulta™ Anterior BioSynthetic Support System and Avaulta™ Posterior BioSynthetic Support System are intended as single-use devices. The mesh and introducers are sterilized by ethylene oxide. Do not resterilize. Discard introducers and any unused mesh following the procedure.

STORAGE

Recommended storage conditions: between 2°-40°C (36°-105°F), in a dry area.

GUARANTEE

SOFRADIM Production certifies that all precautions have been taken in the choice of materials and manufacturing methods for this product. SOFRADIM Production disclaims all liability in case of loss, damage or costs directly or indirectly linked to the use of the product. The guarantee terms or restrictions listed here cancel and replace any guarantee which does not appear in the present document, whether express or tacit by means of legislation or any other means whatsoever. SOFRADIM Production is not liable for any other action taken on its behalf by any party with regard to the product and hereby forbids any party to do so.

Manufacturer:
Sofradim Production
116, avenue du Formans
01600 Trévoux, France

Avaulta™

ANTERIOR BIOSYNTHETIC SUPPORT SYSTEM

AVAULTA™ ANTERIOR BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX
REF 486010
XXXX-XX
XXXX-XX

AVAULTA™ ANTERIOR BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX
REF 486010
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AVAULTA™ ANTERIOR BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX
REF 486010
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XXXX-XX

AVAULTA™ ANTERIOR BIOSYNTHETIC SUPPORT SYSTEM
LOT XXXXXXXX
REF 486010
XXXX-XX
XXXX-XX

Rx only

CE 0459

SOFRADIM

BARD

découpe 167*199 (zone grise non imprimée)

Avaulta™

BIOSYNTHETIC SUPPORT SYSTEM

GB US CAUTION: To be hydrated a few seconds in the original blister before use by complete immersion in sterile physiological serum.

F ATTENTION : Avant emploi, réhydrater dans le blister d'origine par immersion complète quelques secondes dans du sérum physiologique.

D ACHTUNG : Vor dem Gebrauch, einige Sekunden in der Originalpackung durch komplette Versenkung in einem physiologischen sterilen Serum hydrieren.

I ATTENZIONE : Prima dell'uso, reidratare alcuni secondi nel blister originale per immersione completa in serio fisiologico sterile.

E ATTENCION : Antes del uso, rehidratar algunos segundos en el blister original sumergiéndolas por completo en suero fisiológico estéril.

NL OPGELET : Enhele seconden hydrateren in de originele blister, door de mesh volledig in een fysiologische oplossing onder te dompelen.

P CUIDADO : Para ser hidratado alguns segundos no blister original antes de usar, submergindo totalmente em soro fisiológico esterilizado.

GR ΠΡΟΣΟΧΗ: Πριν τη χρήση να εμβαπτιστεί πλήρως για λίγα δευτερόλεπτα σε αποστειρωμένο φυσιολογικό ορό, μέσα στη συσκευασία του.

DK ADVARSEL : Skal vædes i få sekunder, i den originale blister emballage før brug, ved fuldstændig nedsænkning i sterilt fysiologisk saltvand.

S OBSERVERA : Före användning, återfukta den i den ursprungliga blisterförpackningen genom att sänka ned den helt några sekunder i koksaltlösning.

FIN HUOMIO : Ennen käyttöä upottakaa verkko alkuperäisessä kuplapakkauksessa muutamaksi sekunniksi steriiliin keittosuolaliuokseen.

PL OSTRZEŻENIE: Uwodnić siatkę przez około 30 sekund przed użyciem poprzez jej całkowite zanurzenie w sterylnym roztworze fizjologicznym.

H FIGYELMEZTETÉS: Használat előtt hidratálja a hálót kb. 30 másodpercig egy steril fiziológiás oldatba teljesen belemerítve.

CZ POZOR: Před použitím sítku zvlhčujte po dobu asi 30ti vteřin úplným ponořením do sterilního fyziologického roztoku.

TR UYARI: Kullanımdan yaklaşık 30 sanlye önce, ağı steril fizyolojik tuz çözeltisine tamamen batırarak ıslatınız.

Rx only | SINGLE USE | STERILE EO | 2°C 40°C | CE 0459

E 1454 01 - 2005-05-23

SOFRADIM PRODUCTION
116, avenue du Formans
01600 Trevoux, France

Distributed by:
BARD
C. R. Bard, Inc.
Covington, GA 30014
1.800.526.4488

Bard Limited, Forest House
Tilgate Forest Business Park,
Brighton Road, Crawley,
West Sussex RH11 9BP UK
0044 1293 527 888

91

DAVOL

Bard* CollaMend* Implant

Crosslinked Acellular Collagen Matrix

Instructions for Use

Single Use STERILE EO

BARD

*Advancing the Delivery of Health Care.**

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⚠ Read all instructions prior to use.

PRODUCT DESCRIPTION:

Bard CollaMend Implant is a sterile, off-white sheet of lyophilized acellular porcine dermal collagen and its constituent elastin fibers. It is processed to remove all non-collagenous cellular components and is cross-linked to increase strength and endurance. **Bard CollaMend** Implant is double-packaged dry in a Tyvek® envelope within a peel-open aluminum foil pouch, which is impermeable to moisture and oxygen.

Bard CollaMend Implant should be stored in a clean, dry location at room temperature.

The benefits of using **Bard CollaMend** Implant include biomechanical strength, biocompatibility, conformability, and ease of use. The implant incorporates into recipient tissue with associated cell and microvascular ingrowth, forming a strong repair of soft tissue defects.

INDICATIONS:

Bard CollaMend Implant is indicated to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.

CONTRAINDICATION:

Bard CollaMend Implant is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

WARNINGS:

1. **This implant is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.**
2. **This device is for single use only. DO NOT RESTERILIZE. After opening, discard unused portions of the implant.**
3. **If an infection develops, treat the infection aggressively.**
4. **To prevent recurrences when repairing hernias, the implant should be large enough to extend beyond the margins of the defect.**
5. **After use, any unused product and packaging should be treated as a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.**

PRECAUTIONS:

1. Please read all instructions prior to use.
2. Only physicians qualified in appropriate surgical techniques should use this implant.
3. **Bard CollaMend** Implant should only be handled with sterile gloves or non-toothed forceps.

ADVERSE REACTIONS:

Possible complications include seromas, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

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INSTRUCTIONS FOR USE:

HYDRATION:

Bard CollaMend Implant must be completely hydrated before use by immersion in sterile saline solution or sterile lactated ringers solution for a minimum of 3 minutes.

SIZING:

Bard CollaMend Implant may be aseptically trimmed to the required dimensions. It may also be folded or layered to fill the tissue space and shaped to any required contour. However, if layering, it is preferable to cut the material into separate sheets, creating edges, rather than to fold it, presenting maximum number of cut surfaces to body tissue, to enhance penetration by cells and blood vessels. Any unused material should be discarded.

FIXATION:

Bard CollaMend Implant may be fixated in place using sutures (absorbable or non-absorbable) or a mechanical fixation device.

TRACEABILITY:

A traceability label that identifies the type, size and lot number of the implant is enclosed in every package. This label should be affixed to the patient's permanent medical record to clearly identify the device that was implanted.

℞ only

	Contents
	Sterile unless package is damaged or open.
	Rectangle
	Ellipse

Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Sockanossett Crossroad
Cranston, RI 02920
1-401-463-7000 • 1-800-556-6275

Medical Services & Support
Clinical Information Line
1-800-562-0027

PK3792808 058R

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95

DAVOL

Bard* *CollaMend** Implant

Crosslinked Acellular Collagen Matrix

Contents: 1

REF 1175102

10.2cm x 15.2cm
4" x 6"
Ellipse

STERILE EO Single Use

Sterile unless package is damaged or open.

℞ only

Please see Instructions for Use.

Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Sockanossett Crossroad
Cranston, RI 02920
1-401-463-7000
1-800-556-6275

Medical Services & Support
Clinical Information Line
1-800-562-0027

BARD
Advancing the Delivery of Health Care.*

* +H30311751020 *

* +$$801080541TSTLOT 0 *

LOT 41TSTLOT

EXP 2005-08

PK3792877 057R
0003

Bard* *CollaMend** Implant
10.2cm x 15.2cm / 4" x 6"
Ellipse
REF 1175102
LOT 41TSTLOT

Bard* *CollaMend** Implant
10.2cm x 15.2cm / 4" x 6"
Ellipse
REF 1175102
LOT 41TSTLOT

Bard* *CollaMend** Implant
10.2cm x 15.2cm / 4" x 6"
Ellipse
REF 1175102
LOT 41TSTLOT

Bard* *CollaMend** Implant
10.2cm x 15.2cm / 4" x 6"
Ellipse
REF 1175102
LOT 41TSTLOT

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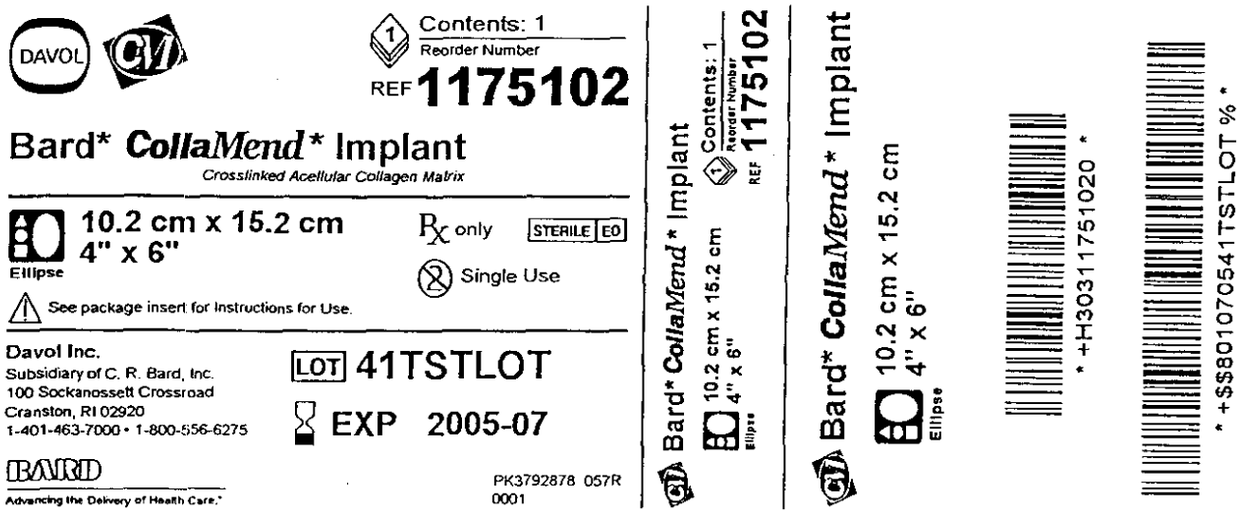
96


DAVOL
Contents: 1
Reorder Number
REF 1175102
Bard* CollaMend* Implant
Crosslinked Acellular Collagen Matrix
10.2 cm x 15.2 cm
4" x 6"
Ellipse
Rx only
STERILE EO
Single Use
See package insert for Instructions for Use.
Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Sockanossett Crossroad
Cranston, RI 02920
1-401-463-7000 • 1-800-556-6275
BARD
Advancing the Delivery of Health Care.
LOT 41TSTLOT
EXP 2005-07
PK3792878 057R
0001
Bard* CollaMend* Implant
Contents: 1
Reorder Number
REF 1175102
10.2 cm x 15.2 cm
4" x 6"
Ellipse
Bard* CollaMend* Implant
10.2 cm x 15.2 cm
4" x 6"
Ellipse
* +H30311751020 *
* +$$801070541TSTLOT % *

000030

97

Exhibit 6

Comparison Table

Comparison Table (Predicate vs. Subject Device)

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

NOTE: **Bold Type – Difference between predicate as currently marketed and subject device.**
Plain Type – Subject device attribute is the same as that of the predicate device as currently marketed.

Attribute	Predicate Device CollaMend Implant K052322	Predicate Device UGYTEX Dual Knit Mesh K051503	Subject Device Avaulta Support System
Intended Use	Reinforcement of tissue during surgical repair	Reinforcement of tissue during surgical repair.	Same
Indications for Use	Reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.	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.	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.
Mesh central section	N/A	Soft knit mesh with porcine collagen film	Soft knit mesh **with and without** porcine collagen **sheet attached to one side of the mesh and an apical flap for apical fixation**
Mesh markers	N/A	None	**Blue markers on the midline and in lateral arms**
Mesh lateral arms	N/A	Strong knit mesh	Strong knit mesh
Mesh characteristics	N/A	Porous, open, monofilament knit that allows trimming of the implant and tissue ingrowth	Same
Collagen	Crosslinked, acellular, lyophilized porcine dermal collagen sheet	Porcine collagen film	Crosslinked, acellular, lyophilized porcine dermal collagen sheet
Collagen thickness	1.0mm	N/A	0.5mm
Collagen porosity	Solid sheet	N/A	1.8mm holes
Implant shape	N/A	Rectangular and precut for anterior and posterior repair with an apical flap on the anterior	Precut for anterior and posterior repair with **apical flap on both**
Implant method of fixation	N/A	Staples, sutures or tension free	Same
Implant sterilization	EtO	EtO	Same

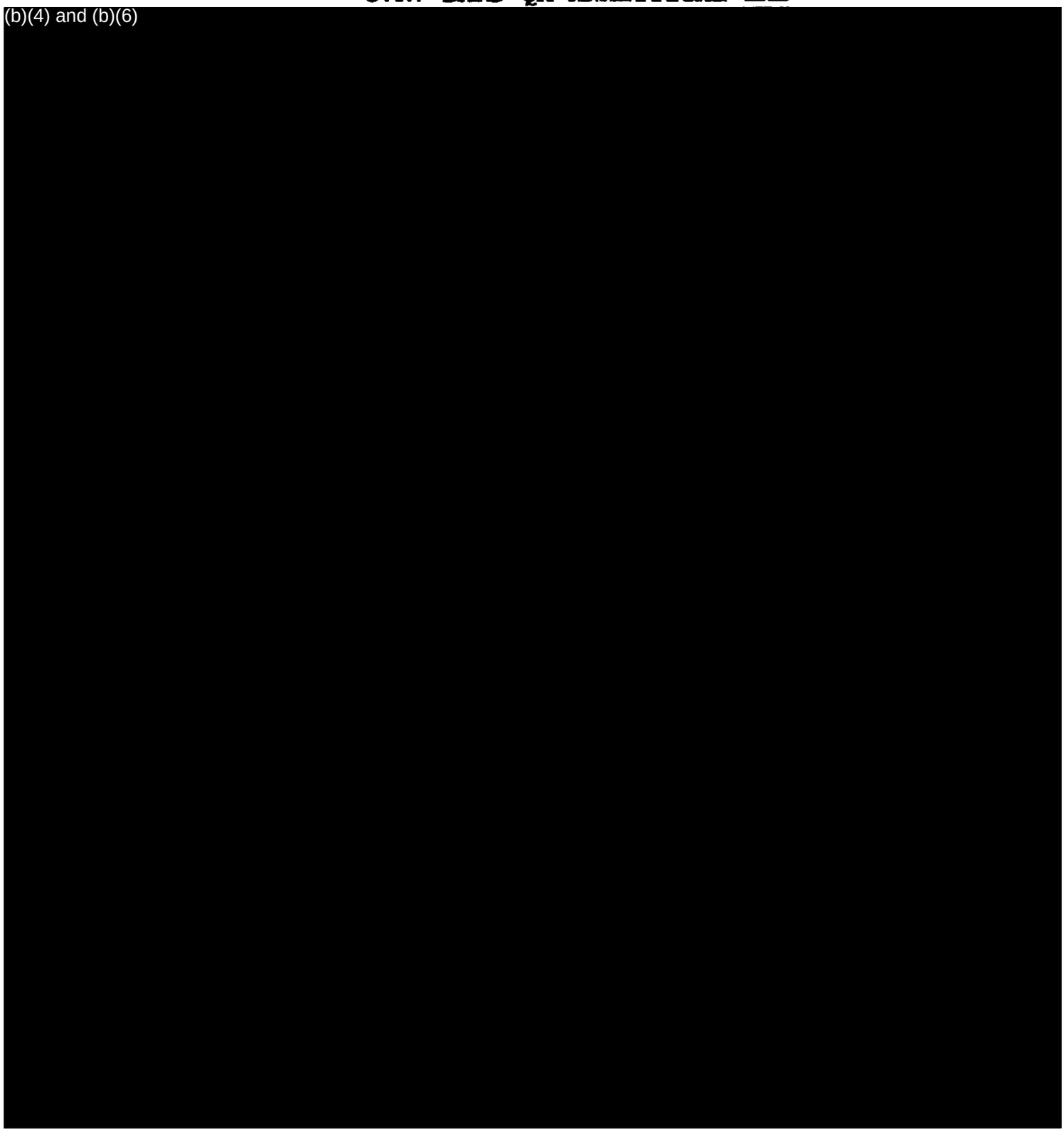
Exhibit 7

Chemical Characterization and Biocompatibility Test Reports

- Gas Chromatography Mass Spectroscopy Characterization
- USP Physicochemical
- Cytotoxicity – MEM Elution Method
- Sensitization – Murine Local Lymph Node Assay
- Irritation – ISO Vaginal Irritation Study

C.R. BARD QA ANALYTICAL LAB

(b)(4) and (b)(6)



(b)(4) and (b)(6)

[redacted]

102

(b)(4) and (b)(6)

[redacted]

(b) (4) REPORT

TEST FACILITY:

(b) (4)

SPONSOR:

(b) (4)

(b) (4)

STUDY TITLE:

(b) (4)

TEST ARTICLE:

(b) (4)

IDENTIFICATION NO.:

(b) (4)

(b) (4)

TABLE OF CONTENTS Page

Summary

(b)(4) and (b)(6)

[redacted]

/pfk

(b) (4)

[redacted]

FOI

1. Introduction

(b) (4)

2. Materials

(b) (4)

(b) (4)

FO

3. Test System

(b) (4)

4. Animal Management

(b) (4)

(b) (4)

(b) (4)

[redacted]

5. Methods

(b) (4)

[redacted]

6. Results

(b) (4)

[redacted]

(b) (4)

[redacted]

7. Conclusion

(b) (4)

8. Quality Assurance

(b) (4)

9. Proposed Dates

(b) (4)

10. Records

(b) (4)

11. References

(b) (4)

12. Protocol Changes

(b) (4)

(b) (4)

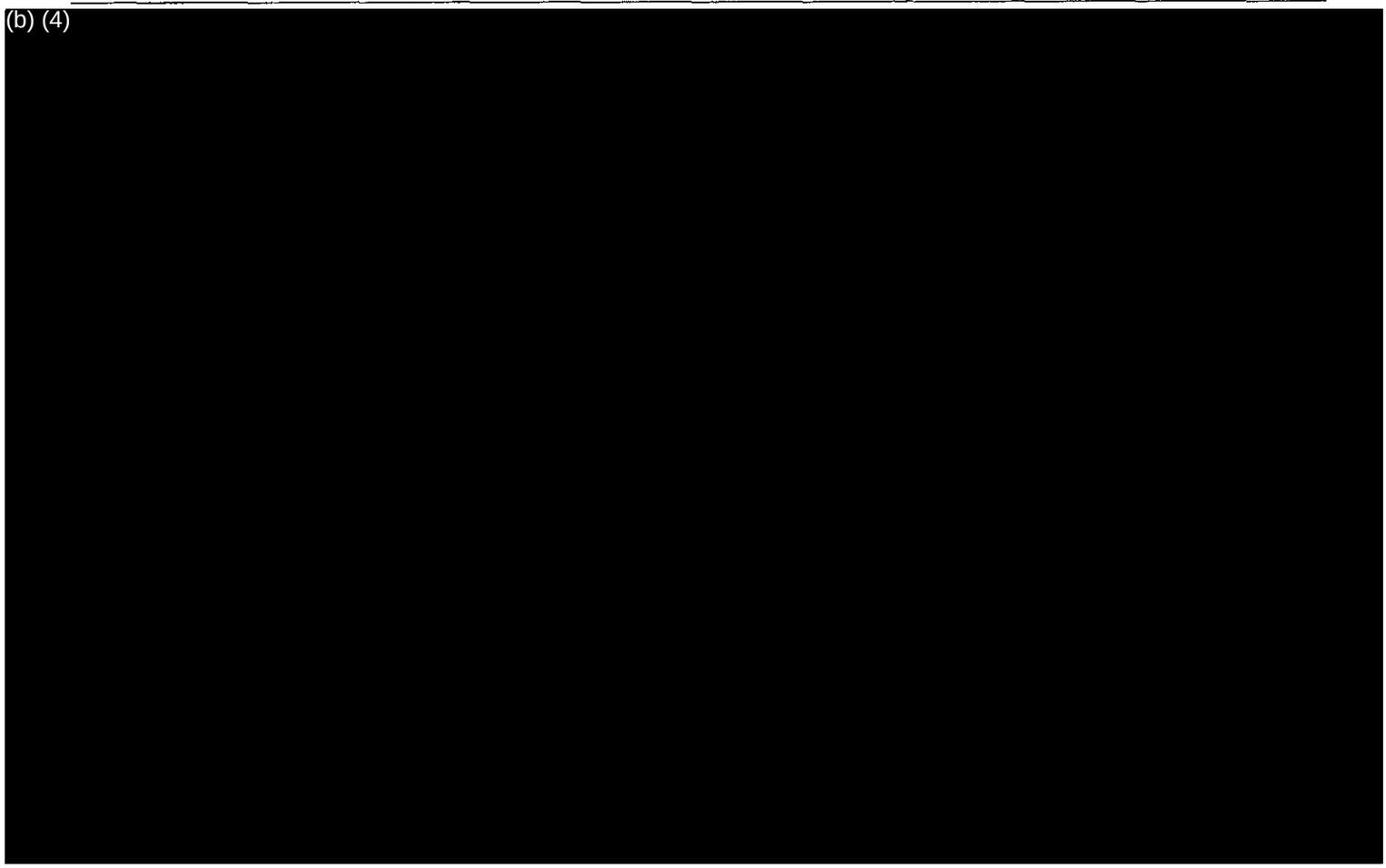
Appendix 1 - Individual Body Weight And Health Observations

(b) (4)

(b) (4)

Appendix 2 - Individual Data (DPM)

(b) (4)



(b) (4)

Certificate Of Quality Assurance Inspections

(b) (4)

(b) (6)

(b) (4)

(b) (4)

(b) (4) REPORT

TEST FACILITY:

(b) (4)

SPONSOR:

(b) (4)

(b) (4)

STUDY TITLE:

(b) (4)

TEST ARTICLE:

(b) (4)

IDENTIFICATION NO.:

(b) (4)

(b) (4)

TABLE OF CONTENTS Page

(b) (4)

[redacted]

Summary

(b)(4) and (b)(6)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

1. Introduction

(b) (4)

[redacted]

2. Materials

(b) (4)

[redacted]

(b) (4)

[redacted]

3. Test System

(b) (4)

[redacted]

4. Animal Management

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

5. Methods

(b) (4)

6. Evaluation

(b) (4)

7. Results

(b) (4)

(b) (4)

8. Conclusion

(b) (4)

9. Quality Assurance

(b) (4)

10. Proposed Dates

(b) (4)

11. Records

(b) (4)

12. References

(b) (4)

13. Protocol Changes

(b) (4)

(b) (4)

Appendix 1 - ISO Vaginal Irritation Study Microscopic Evaluation

(b) (4)

(b) (6)

(b) (4)

Certificate of Quality Assurance Inspections

(b) (4)

[redacted]

(b) (6)

[redacted]

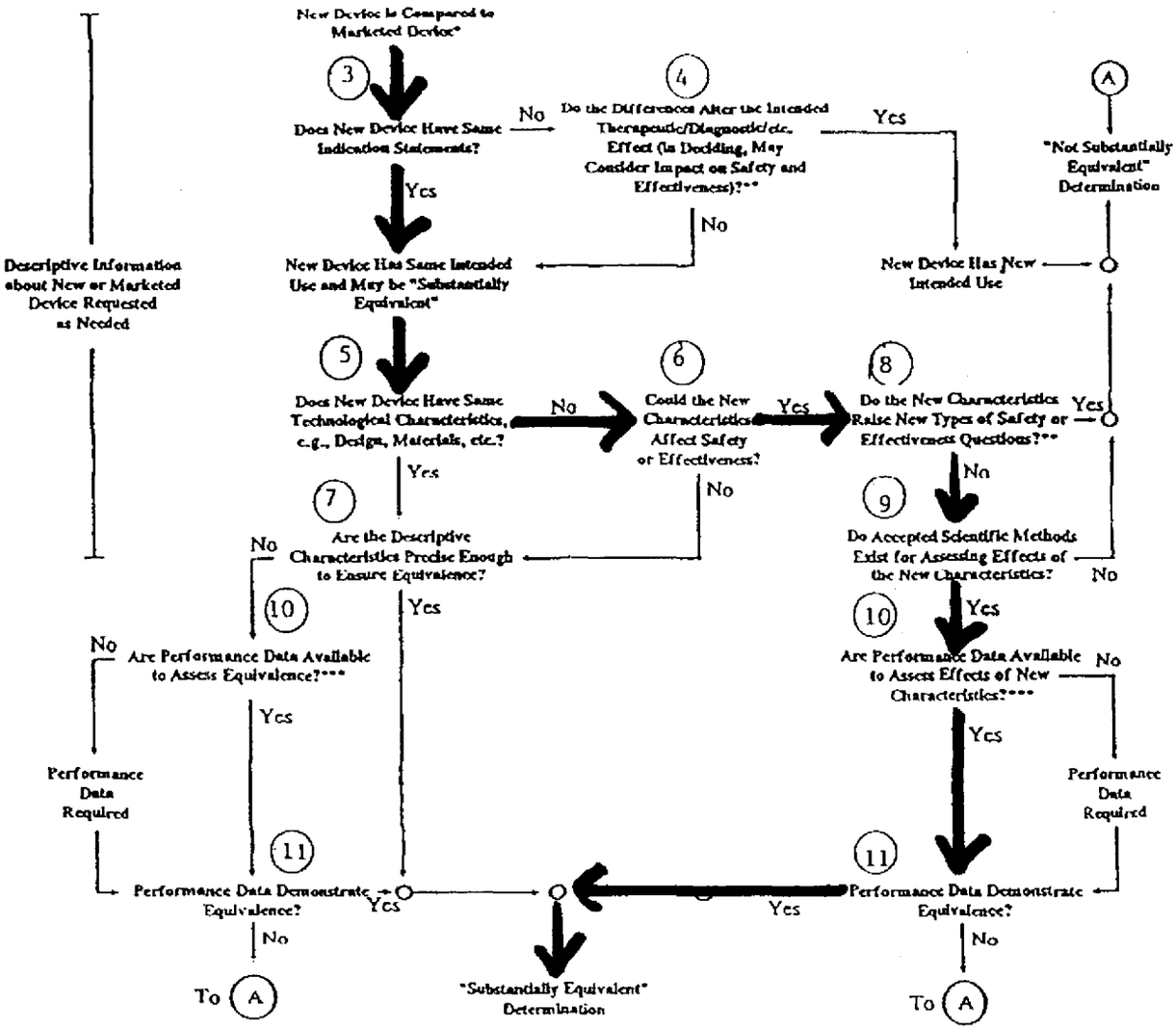
(b) (4)

[redacted]

Exhibit 8

510(k) Substantial Equivalence Decision Tree

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



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

Exhibit 9

Kit Component Certification

I certify that the manual introducers provided in Avaulta Support System kits are Class I devices exempt from premarket notification (21 CFR 878.4800) consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemption.

The introducers are purchased bulk, non-sterile to a Bard specification. The introducers are packaged, sealed, labeled and sterilized by Bard.

Signature: John C. Knorpp

John C. Knorpp
Manager, Regulatory Affairs

Date: 11-13-06

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2007

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.

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

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)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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

510(k) Number K063712

(Recommended Format 11/13/2003)

Rhodes, Stephen

From: Hudson, Peter
Sent: Monday, March 19, 2007 3:24 PM
To: Stuart, Julie (Brandi)
Cc: Rhodes, Stephen; Shulman, Marjorie G.
Subject: Corrected SE letter

Julie, Marjie,

K063712, Bard's Avaulta Surgical mesh was cleared on March 12, 2007. Only one product name, the Solo Support System, was identified in the SE letter. The 510(k) contained information on the Solo Support System but also on the Avaulta Plus Biosynthetic Support System and this information was considered in determination of safety and effectiveness of the 2 devices. Therefore a corrected SE letter identifying both devices should be issued. Thanks.

Peter

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.

5

Page 2 - Mr. John Knorpp, RAC

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

Enclosure

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-410	[illegible]	3/16/07						
HFZ-410	[illegible]	3/2[illegible]						
[illegible]	[illegible]	3/25/[illegible]						

6

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:PLH:tlm:3-16-07

Last Updated: Brandi Stuart 1/31/07

(1)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) C. Updegrove Ph.D.

Subject: 510(k) Number K063712

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices NA

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☒ YES ☐ NO Material of Biological Origin ☒ YES ☐ N

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 d

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

79 FTL Surgical Mesh, Class II
878.3300

Review: Steph Blanchard PRSB 3/9/07
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] DRO Director 3/10/07
(Division Director) (Date)

Revised 4/2/03

4

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?	N/A	
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	—	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

(8)

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 063712

Reviewer: C Anderson, Ph.D.

Division/Branch: OGRND IPRSB

Device Name: Avaulta Support System

Product To Which Compared (510(K) Number If Known): K061503

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		✓	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

7

(9)

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue: Device design & components nearly identical to predicates

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(K) MEMORANDUM

TO: K063712

FROM: Peter L. Hudson, Ph.D.
ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

DATE: 3/6/07

SUBJ: Avaulta Support System
C.R. Bard, Inc.
Mr. John C. Knorpp
PHONE: 678-342-4920
FAX: 770-788-5513
Email: john.knorpp@crbard.com

Recommendation: Substantially equivalent
Procode: FTL
Class: II
Regulation Number: 878.3300
Regulation Name: Surgical mesh

REVIEW:

1. **Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)**

Subject Device

The [device] 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.

Predicate device(s)

UGYTEX® Dual Knit Mesh (marketed as Avaulta™ Biosynthetic Support System), K051503
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.

Bard® Collamend™ Implant, K052322
Reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.

Discussion of whether the intended use/indications are the same

The subject device's indications for use are identical to the UGYTEX® surgical mesh indications for use and therefore are substantially equivalent.

2. **Comparison of the Technological Characteristics (Design, Materials, Sizes, Features, Shapes, etc.) of the Subject Device and Predicate(s)**

Subject Device

The device is described as being intended for use in anterior and posterior vaginal wall prolapse repair surgical procedures. The device will be offered in the following 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 Solo Support System is composed of a pre-cut synthetic mesh implant. The Plus Biosynthetic Support System is composed of the same pre-cut synthetic mesh implant with a porcine collagen sheet covering one side of the central section. The central, soft section of the mesh is intended to provide compliant organ support while the stronger knitted arms are intended to provide strength for tension free fixation of the device. In the collagen-coated meshes, the arms are not coated. The device is provided with an introducer for placement; introducers are class I, exempt.

Design

The mesh is composed of monofilament polypropylene knitted so as to prevent unraveling irrespective of how the mesh may be cut or trimmed. The geometries of the anterior and posterior device forms conform to their respective uses. The knit pattern for the anterior and posterior device forms is the same; the devices differ only in the width dimension.

Central mesh section: soft knit consisting of a 3 mil fiber for the base mesh and a 4 mil inlay fiber for added strength; a blue polypropylene fiber is knit down the center as a midline marker to aid in orientation and placement.

Lateral mesh section (arms): strong knit – 4 mil fiber for the base mesh with a 4 mil inlay fiber for added strength; 2 blue polypropylene fibers knit in the arms on one side to aid in orientation and placement

Collagen sheet (Plus Support System): the lyophilized collagen sheet is crosslinked and is attached to the central section using a polypropylene fiber; the collagen sheet contains 1.8 mm pores to allow tissue ingrowth.

The UGYTEX® predicate is described as:

The device is a monofilament, nonabsorbable, polypropylene mesh. It has a soft knit in the

central section and a strong knit in the lateral sides. The central, soft section is coated with a hydrophilic, collagen film used previously in the predicate comparator, K033376. The lateral sections of the mesh are not coated with the film. The following device configurations will be provided:

- Dual knit mesh: a rectangular sheet that can be trimmed to a desired size and shape
- Dual knit, anterior repair system: a pre-cut device for anterior vaginal wall prolapse repair accompanied by an introducer to facilitate placement
- Dual knit, posterior repair system: a pre-cut device for posterior vaginal wall prolapse repair accompanied by an introducer to facilitate placement

- The introducer provided with the meshes is a Class I, exempt, manual surgical instrument (21 CFR 878.4800). The sponsor has provided the kit certification statement.

Collagen sourcing information

Tissue/species source: (b) (4)

Herd:

Vaccination:

Veterinarian inspections:

Feed:

Abattoir USDA approved:

BSE-free country:

Collagen processing

(b) (4)

From K052322:

Manufacturing Process

- (b) (4)
- (b) (4)

- (b) (4)
- (b) (4)
- (b) (4)
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- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

In response to the following deficiency:

(b) (4)

Please provide a material safety data sheet (MSDS) for (b) (4) *as well as toxicology information for the chemical. Please provide an analysis of the potential toxicity of* (b) (4) *when residual chemical quantitative analyses are complete.*

(b)(4) and (b)(6)

- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

(b) (4)

(b) (6)

(b) (4)

(b) (4)

The viral inactivation validation results cited from K052322 follow:

(b) (4)

- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Original deficiency:

(b) (4)

Please provide the following information:

- (b) (4)

(b) (4)

  - (b) (4)
  - (b) (4)
  - (b) (4)

- (b) (4)

(b) (4)

- (b) (4)

(b) (4)

(b) (4)

(b) (4)

With respect to chemical residuals:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b)(4) and (b)(6)

(b)(4) and (b)(6)

(b) (4)

(b) (4)
[redacted]

Recommendations
Specific attention should be paid to toxicity/sensitization of the biologic tissues exposed to the product. I do not see an indication for any other biochemical or clinical monitoring at this time."

Biocompatibility results indicated that the product was safe and non-toxic. No additional information is necessary.

Residual chemicals in the homogenized material and final product will be assessed via various analytical techniques, e.g., GC, ICP, FIA, etc. When reporting the residual chemicals determined by each technique, please be sure to report the assay's sensitivity.

The sponsor identified the detection limits in their reports found in exhibits 8 and 9. No additional information is required.

Device physical strength and dimensional characterizations
Testing was conducted in accordance with recommendations identified in FDA's Surgical Mesh guidance document. Comparisons were made to the UGYTEX® predicate device.

Parameter	Avaulta		UGYTEX	
	Mesh center	Mesh arms	Center	Arms
(b) (4)	[redacted]			

Tensile strength is measured for anterior, proximal and distal arms, and posterior proximal and distal arms – values are referenced in ranges below; hybrid (collagen) device form values were equivalent

	Anterior P/D	Posterior P/D	Anterior P/D	Posterior P/D
Tensile strength	(b) (4) [redacted]			

Device stiffness measurements are made in (b) (4) orientations: (b) (4) [redacted]

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	Mesh center	Avaulta Mesh arm	Hybrid	UGYTEX Center
(b) (4)	[redacted]			

Predicate Device(s)
UGYTEX® Dual Knit Mesh (marketed as Avaulta™ Biosynthetic Support System), K051503

Discussion of whether the subject device has a significant change in technological characteristics
A difference noted between the subject device and the UGYTEX® Dual Knit Mesh is that the collagen used on the UGYTEX device is a clear film whereas the subject device uses a lyophilized, crosslinked collagen sheet. The sheet is identified as the same as that used in Bard's Collamend Implant product (K052322). The physical strength and dimensional information of the subject and predicate surgical meshes is substantially equivalent. As noted above, the device design/configuration is very similar to the UGYTEX® Dual Knit Mesh.

3. **Comparative Data (*in vitro*, animal and/or clinical)**

Safety Data - Subject Device
The sponsor cites the use of "natural" polypropylene monofilament fiber in the Sofradim UGYTEX Dual Knit Mesh predicate (K051503) and their own, Bard Soft Mesh (K052155) predicate. They further cite the precedent use of the blue polypropylene monofilament fiber in US Surgical's SurgiPro II Suture, and the collagen of their own predicate mesh, the Bard CollaMend Implant (K052322). They therefore decided to do a selected subset of biological and chemical assessments of the subject device.

For biocompatibility they conducted:

- Sensitization — Pass
- Irritation (vaginal mucosa) — Pass
- Cytotoxicity — Pass

They also conducted USP Physicochemical evaluation and observed passing results. With

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respect to previous biocompatibility evaluation of the collagen component of the device, the sponsor provided the following information in support of the CollaMend product:

The sponsor conducted biocompatibility testing in accordance with the Blue Book memorandum issued May 1, 1995 and the ISO-10993, Biological evaluation of medical devices, part 1: evaluation and testing. The device is correctly identified as a tissue contacting, permanent implant. The device was assessed in the following assays, results provided:

Test	Result
Cytotoxicity	Pass
Systemic toxicity	Pass
Irritation	Pass
Sensitization	Pass
Genotoxicity – (b) (4)	Pass
Genotoxicity – (b) (4)	Pass
Genotoxicity – (b) (4)	Pass
Pyrogenicity – (b) (4)	Pass

Implantation – (b) (4)

Summary

(b) (4)

(b) (4)

(b) (4) week observations

The report indicates that there were no differences between the response to either collagen mesh. The following observations were noted:

- (b) (4)
- (b) (4)
- (b) (4)

(b) (4) week observations

(b) (4)

(b) (4)

(b) (4)

(b) (4)

With regard to a deficiency for the chronic toxicity evaluation:
You are conducting a chronic toxicity evaluation ((b) (4)) (b) (4), however the results have not yet been obtained. Please provide the results of this assessment to complete the safety profile of the device in order for determination of substantial equivalence. The results of these evaluations, e.g., (b) (4) and (b) (4) weeks, will provide additional implantation biocompatibility information to augment the limited information provided in the 4 week implantation study that observed infections in half of the animals.

The sponsor provided the completed study report for (b) (4) weeks and (b) (4) weeks implantation. They argue that ISO 10993 specifies that chronic toxicity evaluations be done for a period of time equivalent to (b) (4) of the animal's life (e.g., (b) (4)). They state that K042026 (Bard CK Parastomal Patch) received FDA clearance based on a (b) (4) week chronic toxicity evaluation.

The sponsor has provided the results of completed (b) (4) and (b) (4) week (b) (4) implantation evaluations. The results at (b) (4) weeks indicated that the (b) (4) . Similar results were observed in the (b) (4) week study. The sponsor has adequately addressed the deficiency and the concerns raised by the study presented in the original application. No additional information is required.

With respect to the polypropylene component, the sponsor's own material from a different device has been evaluated in the following tests (from K052155 review):

- Biocompatibility – Because the proposed device is composed of the same material and produced via a similar manufacturing process as the Bard SpermaTex Mesh (K991637) – the data from that application. These test results include:
-
    - Cytotoxicity Pass
    - Sensitization Pass
    - I.C. Reactivity Pass
    - Acute Systemic Toxicity Pass
    - Genotoxicity Pass
    - Implantation ((b)(4) weeks and (b)(4) weeks) Pass
    - Hemocompatibility Pass
    - Chronic Toxicity ((b)(4) week) Pass

Safety Data - Predicate Device(s)
The testing and results of the sponsor's own predicate products has been identified as evidence for the subject device.

Effectiveness Data – Subject Device
Physical strength and characterization information as identified above serves as surgical mesh effectiveness data for the proposed indications.

Effectiveness Data - Predicate Device(s)
In K052322, the sponsor conducted comparative evaluations of the device to the Permacol and Mersilene predicates. Physical and performance characteristics were assessed. The sponsor conducted testing in accordance to recommendations found in the CDRH Surgical Mesh guidance document. To support effectiveness determinations in the sponsor's Bard Soft Mesh (K052155) predicate, physical strength and characterization information was provided.

Discussion of whether the data demonstrate that the subject device is as safe and effective as the predicate(s)
The subject device's components, i.e., polypropylene mesh and porcine collagen, have been adequately assessed via biocompatibility determinations for safety and via physical strength and characterization assessments for prediction of effectiveness. The product is substantially equivalent with respect to predicate surgical meshes for safety and effectiveness.

4. **Does the product contain drugs or biologicals?** No, the product contains porcine dermal collagen.

5. **Sterilization**

Sterilization method:	Ethylene Oxide
Validation method:	ANSI/AAMI/ISO 11135 – 1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization

Packaging:	The implant tray will be placed in a foil/foil pouch with a Tyvek header, i.e., foil to foil. The foil pouch with foil to foil heat seal provides a long-term moisture barrier. The tray is then placed within a Tyvek®/film pouch. The implant and introducer will be placed in a corrugated box.
SAL:	10^{-6}
EtO residuals:	In conformance with limits identified in ANSI/AAMI/ISO 10993-7: 1995 and TIR No. 19-1998; ethylene oxide dose (20 mg/first 24 hrs., conc. not to exceed 250 ppm)
Pyrogenicity claims -	The sponsor has conducted the LAL endotoxin assessment and found the device ((b) (4)) to be <(b) (4) [redacted], with respect to the collagen device component.

With respect to endotoxin testing for the rest of the surgical mesh, the issue was raised by (b) (6) [redacted] in review of K052155. The issue was discussed internally at ODE. In the final analysis, FDA determined that it did not have guidance documentation or regulatory statute at this time to cause the sponsor to conduct lot-to-lot endotoxin determinations. A draft sterilization guidance is under revision currently that will deal with the endotoxin testing requirement for implanted medical devices. Until FDA issues a testing requirement, for non-direct blood path contacting devices, if it is not labeled pyrogen-free, no additional testing is required.

6. **Discussion of Labeling Adequacy**

(Prescription):
Package Insert (exhibit 4)
Carton/Pouch Labels (exhibit 4)

The product labeling is equivalent to predicate surgical mesh labeling.

7. **Labeling claims (other than any drug claims reviewed above)**

The device will initially be marketed with a one year expiration date, i.e., 5 yr accelerated of mesh plus 1 year Collamend collagen coating

8. **Has sponsor provided all administrative requirements?**

- Truthful and Accurate Statement (pg. 6)
- 510(k) Summary (exhibit 2)
- Indication for Use Page (pg. 7)
- FDA Establishment Registration Number: 1018233

9. **Analysis of the Equivalence of the Subject and Predicate(s)**

The device is technologically, safety and effectiveness-wise substantially equivalent to predicate surgical mesh products indicated for repair of (b) (4) [redacted]. No additional

information is necessary.

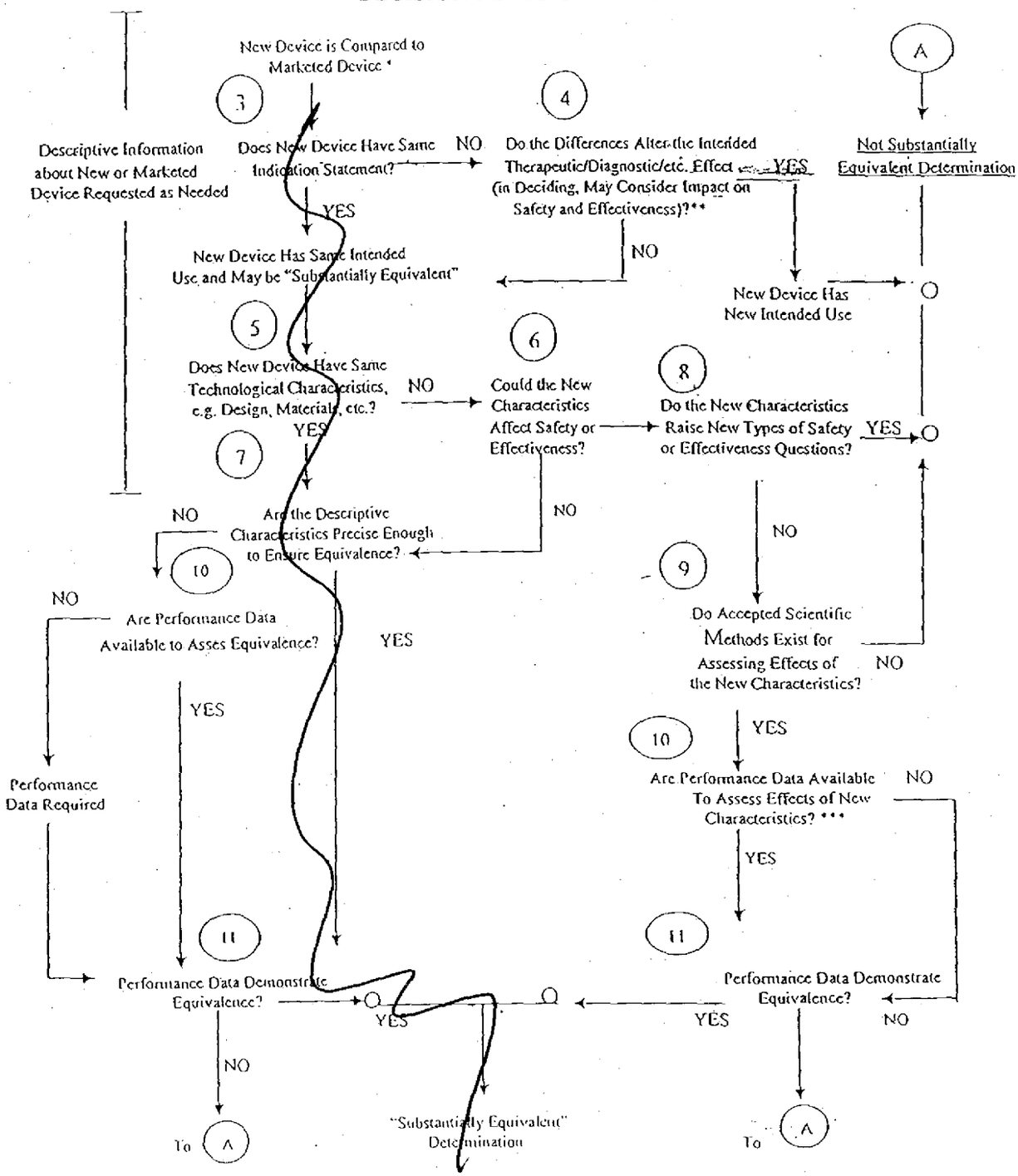
C L Hyden, Ph. D. 3/6/07

Name Date

Plastic and Reconstructive Surgery Devices Branch

(2)

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.

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