

OCT 07 2008

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**SECTION 7.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**A. Submitter Information**

Submitter's Name: Davol Inc.  
Address: Subsidiary of C. R. Bard, Inc.  
100 Sockanossett Crossroad  
Cranston, RI 02920  
Telephone: (401) 215-2252  
Fax: (401) 215-2031  
Contact Person: Stephanie Baker  
Date of Preparation: March 20, 2008

**B. Device Name**

Trade Name: Bard 3DMAX Mesh  
Common/Usual Name: Surgical Mesh  
Classification Name: Surgical Mesh

**C. Predicate Device Name**

Trade name: Bard Mesh (Davol Inc.)  
Trade name: Bard 3DMAX Mesh (Davol Inc.)  
Trade name: Usher's Marlex Tubular Mesh (Davol Inc.)

**D. Device Description**

The modified Bard 3DMAX Mesh is anatomically designed to fit the inguinal anatomy. The device is curve shaped and preformed with sealed edges that allow for easier positioning of the device than a traditional flat sheet of mesh in a laparoscopic inguinal hernia repair. The device is constructed of knitted polypropylene monofilaments 7.5 millimeters in diameter. The knit construction allows the mesh to be stretched in both directions in order to accommodate and reinforce tissue defects. The device contains an orientation marker in an M shape with an arrow to facilitate mesh positioning and placement.

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PREMARKET NOTIFICATION FOR THE BARD 3DMAX MESH

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**E. Intended Use**

The modified Bard 3DMAX Mesh is a sterile, single use device indicated to reinforce soft tissue where weakness exists e.g. for repair of hernias and chest wall defects. The intended use for the modified device is exactly the same as the predicate devices, 3DMAX Mesh, Bard Mesh and Usher's Marlex Tubular Mesh.

**F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use**

The modified 3DMAX Mesh device and the currently marketed 3DMAX Mesh and Bard Mesh devices are all indicated to reinforce soft tissue where weakness exists e.g. for repair of hernias and chest wall defects. Usher's Marlex Tubular Mesh is also indicated for use in hernia repair.

In addition, all products are similar in technological characteristics and performance. The modified 3DMAX Device differs from the currently marketed 3DMAX device in medial marker material only. The medial marker material used in the modified 3DMAX device will be purchased from a different vendor. The main components of the medial marker, polypropylene and Phthalocyaninato(2-) copper dye will remain the same. However, these items will be purchased from a different vendor and extruded to form a dyed polypropylene monofilament. As a result, there may be slight variations in the medial marker material formulation used in the modified device as compared to the currently marketed 3DMAX Mesh medial marker. These slight variations were evaluated through biocompatibility testing as well as laboratory testing.

**G. Performance Data**

Biocompatibility testing was performed on the modified 3DMAX device. Testing performed to date indicates that changes made to the 3DMAX device do not impact its biocompatibility profile. In addition, laboratory testing was performed to compare the modified 3DMAX Mesh device to the currently marketed 3DMAX Mesh and Bard Mesh devices. The results show that the modified device is substantially equivalent to the currently marketed predicate devices. Therefore, based on laboratory testing and biocompatibility data, the modified 3DMAX device is safe and effective for its intended use.

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PREMARKET NOTIFICATION FOR THE BARD 3DMAX MESH

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 07 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Stephanie Baker  
Senior Regulatory Affairs Associate  
Davol Incorporated  
Subsidiary of C.R. Bard, Incorporated  
100 Sockanossett Crossroad  
Cranston, Rhode Island 02920

Re: K081010  
Trade/Device Name: Bard 3DMAX Mesh  
Regulation Number: 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: II  
Product Code: FTL  
Dated: August 6, 2008  
Received: August 7, 2008

Dear Ms. Baker:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

K081010

INDICATION FOR USE STATEMENT

510(k) Number (if known): K081010  
Not Known

Device Name: **Bard 3DMAX Mesh**

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

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 Anesthesiology, General Hospital,  
Infection Control, Dental Devices

*Neil R. O'Brien for rkr*  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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

510(k) Number K081010