

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

DEC - 8 2009

**A. Submitter Information**

Submitter's Name: Davol Inc.  
 Address: Subsidiary of C.R. Bard, Inc.  
 100 Crossings Boulevard  
 Warwick, RI 02886

Telephone: (401) 825-8582  
 Fax: (401) 825-8765  
 Contact Person: Gail Dow  
 Date of Preparation: November 3, 2009

**B. Device Name**

Trade Name: Bard® PERFIX™ Light Plug  
 Common/Usual Name: Surgical Mesh  
 Classification Name: Surgical Mesh, Polymeric

**C. Predicate Device Name**

Trade name: Bard® Soft Mesh (Davol Inc.)  
 Trade name: Bard® Mesh Dart (Davol Inc.)  
 Trade name: Bard® PERFIX™ Plug (Davol Inc.)  
 Trade name: Mersilene Mesh (Ethicon, Inc.)

**D. Device Description**

The Proposed Product, Bard® PERFIX™ Light Plug is a pre-formed three-dimensional (cone shape) device constructed of a fluted outer layer and multiple inner layers of mesh attached at the tip. The device has a large pore design and is constructed of knitted polypropylene monofilaments. The pores in the mesh allow for tissue ingrowth. A separate flat, pre-shaped onlay patch (2.3" x 5.4") will be packaged with each device. The Bard® PERFIX™ Light Plug will be offered in a range of sizes with the largest being the extra large PerFix™ Plug 1.5" x 2.0" (4.1cm x 5.0cm). The extra large size consists of three (3) preformed medium shells held in place, side by side, inside a pre-formed large shell. The small, medium and large sizes consist of an outer cone with 2 pieces of mesh (petals) to help the plug maintain its fluted form. The inner petals and cones are sewn together at the tip with a single polypropylene monofilament thread.

## E. Intended Use

The Proposed Product, Bard® PERFix™ Light Plug, is a sterile, single use device indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

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

Bard® PERFix™ Light Plug and the Predicates, Bard® PERFix™ Plug, Bard® Mesh Dart, Bard® Soft Mesh and Ethicon Mersilene Mesh devices are all indicated for use in the repair of hernia defects. Unlike the Predicate Soft Mesh, the Proposed PERFix™ Light Plug is not indicated for the repair of chest wall defects.

The same lightweight large pore polypropylene mesh used to construct the Predicate Soft Mesh is a major component of the Proposed PERFix™ Light Plug. Both are made from the same polypropylene monofilaments with a diameter of approximately 0.0048 inches. The Proposed PERFix™ Light Plug has similar physical attributes and performance characteristics as the Predicates PERFix™ Plug, Mesh Dart, Soft Mesh, and Mersilene Mesh. Furthermore, it has similar materials and manufacturing methods as the Predicate PERFix™ Plug.

The key differences in the Proposed PERFix™ Light Plug compared to the Predicates PERFix™ Plug and Mesh Dart are the diameter of the polypropylene monofilament and the knit pattern of the mesh. The Predicates PerFix™ Plug and Mesh Dart are both made from the same knitted polypropylene monofilament with a diameter of 0.0063 inches whereas the Proposed PERFix™ Light Plug is made of a lighter weight mesh reducing the amount of material used. Compared to traditional monofilament polypropylene meshes as in the Predicates PerFix™ Plug and Mesh Dart, the Proposed PERFix™ Light Plug is constructed from monofilaments with a diameter of approximately 0.0048 inches. However, the weights (grams/square inch) of Mersilene Mesh (0.0274) and Soft Mesh (0.0282) are comparable to the PerFix™ Light Plug (0.0380).

In addition, similar to the Predicate PerFix™ Plug, the Proposed PERFix™ Light Plug will be packaged with a separate flat pre-shaped onlay patch which is the same exact device that is currently marketed as the predicate Bard® Soft Mesh Pre-shaped device. The only differences in the onlay patch in the Proposed Product than the onlay patch that is packaged with the Predicate PerFix™ Plug is that it does not have a spermatic cord opening, is larger in size, and will be made from the same lighter weight polypropylene mesh as the Predicate Soft Mesh.

Similar to the Predicates PerFix™ Plug and Mesh Dart, the Proposed Product is pre-formed and three dimensional in design unlike the Predicates Mersilene Mesh and Soft Mesh, which are flat mesh sheets.

The Predicate Mesh Dart consists of a circular flat base, which is a single layer of mesh, and a conical tip which is a double layer of mesh. The circular flat base and cone are attached together with a single polypropylene monofilament thread whereas the Proposed PERFix™ Light Plug and the Predicate PERFix™ Plug is packaged with an unattached onlay patch.

#### **G. Performance Data**

Laboratory bench testing was performed to assess the effects of the new characteristics of the Proposed PERFix™ Light Plug. These tests compared the Proposed Product against the Predicates Soft Mesh, PERFix™ Plug and Mersilene Mesh. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" (March 2, 1999), tests included physical and performance evaluations of the products in terms of thickness, pore size, density, stiffness, tensile strength, percent elongation, suture pullout strength, burst strength and tear resistance. Laboratory testing discussed in this submission demonstrate that the material chosen and the design utilized in manufacturing the PERFix™ Light Plug is substantially equivalent to the referenced Predicates.

Additionally, biocompatibility testing was completed on the polypropylene material used in the Proposed PERFix™ Light Plug and has received acceptable results.

The results show that the Proposed Product is substantially equivalent to the currently marketed Predicate Products. Therefore, based on laboratory testing and biocompatibility data, the Proposed Product, PERFix™ Light Plug, is safe and effective for its intended use.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Davol Inc.  
Subsidiary of C.R. Bard, Inc.  
% Ms. Gail Dow  
Regulatory Affairs Associate  
100 Crossings Boulevard  
Warwick, Rhode Island 02886

DEC - 8 2009

Re: K092032  
Trade/Device Name: Bard® PerFix™ Light Plug  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: Class II  
Product Code: FTL  
Dated: November 10, 2009  
Received: November 12, 2009

Dear Ms. Dow:

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 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

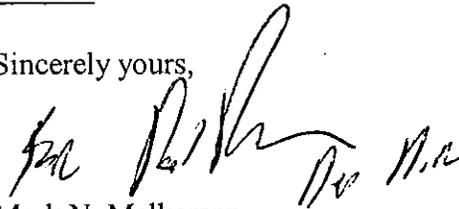
Page 2 - Ms. Gail Dow

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

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

Enclosure

K092032

INDICATION FOR USE STATEMENT

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

Device Name: **Bard® PERFix™ Light Plug**

Indications for Use: The Bard The PerFix™ Light Plug is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

Prescription Use   X    
Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)  
Subpart C)

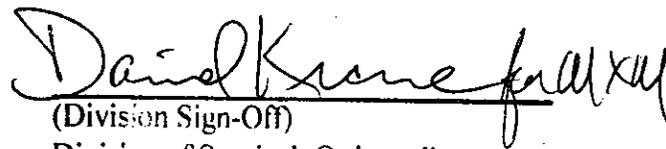
AND/OR

Over-The-Counter  
(21 CFR 801

(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 Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K092032