K102766
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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary is provided per the requirements of section 807.92(c). DEC 16 2010

Submitter Information:

Submitter's Name:	Davol, Inc., Subsidiary of C. R. Bard, Inc.
Address:	100 Crossings Boulevard Warwick, RI 02886
Telephone:	(401) 825-8575
Fax:	(401) 825-8763
Contact Person:	Keti Sino

Device Name:

Trade Name:	Composix™ L/P Mesh with Echo PS™ Positioning System
Common/Usual Name:	- Surgical Mesh - Endoscope & Accessories - Mesh Deployment Balloon
Classification Name:	- Mesh, Surgical, Polymeric - Mesh Deployment Balloon - Laparoscope, General & Plastic Surgery
Classification Code:	- Class II, § 878.3300, Product Code FTL - Class II, § 878.3300, Product Code OQL - Class II, § 876.1500, Product Code GCJ

Predicate Device Names:

- Bard Composix® L/P Mesh, K061754 (Davol Inc.), FDA cleared on 10/23/2006
- **Surgical Structures** *Mesh* GPS™ Deployment Balloon, K092726, FDA cleared on 03/15/2010

Device Description:

The proposed Composix™ L/P Mesh with Echo PS™ Positioning System is comprised of a hernia repair mesh with a pre-attached mesh positioning system (mesh deployment balloon).

The mesh, Composix™ L/P, is a low profile, nonabsorbable, sterile prosthesis designed for the reconstruction of soft tissue deficiencies, previously cleared under K061754. It is constructed of one layer of large pore polypropylene mesh and one layer of expanded polytetrafluoroethylene (ePTFE) stitched together with PTFE monofilament.

The Composix™ L/P Mesh described above will be preassembled with the Echo PS™ Positioning System, a removable mesh deployment balloon, previously cleared under K092726. The positioning system is designed to help facilitate laparoscopic deployment, including unrolling, positioning, and placement of the Composix™ L/P Mesh. Additionally, all sizes of the proposed product will be packaged with an Introducer Tool. The Introducer Tool consists of a metal tines/T-cap assembly which is used to roll the proposed device in order to facilitate laparoscopic introduction. The Introducer Tool is identical to that included and cleared under the Composix® L/P Mesh K061754.

Intended Use:

The Composix™ L/P Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. The Echo PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prosthetics during laparoscopic hernia repair.

Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

The Composix™ L/P Mesh and the predicate mesh have the same indication: reinforce soft tissue, i.e., repair of hernias and chest wall defects. The proposed product has the same intended use, physical attributes, performance characteristics, and materials as the predicate Bard Composix™ L/P Mesh.

The proposed Composix™ L/P Mesh with Echo PS™ Positioning System simply combines two previously cleared devices: K061754 (which included the Introducer Tool) and K092726, the predicate mesh positioning system. However, for optimal functionality in combination with the Composix™ Mesh that is part of the proposed product, two changes have been made to the positioning system. These modifications include a change to the shape of the positioning system and a change to the type of inflation assembly that is to be used with the positioning system. Similar to its predicate device, the Echo PS™

Positioning System has an inflatable channel or tubular structure. However, the predicate device shape was based on a universal design concept in order for it to be compatible with currently marketed mesh devices from various manufacturers, whereas the proposed product is provided in an oval shaped to better match the shape and configuration of the Composix™ L/P Mesh. The second change addresses the positioning system inflation assembly which has been updated to a syringe inflation apparatus, replacing the original bulb type inflation apparatus, as used for the predicate device positioning system. The Echo PS™ Positioning System maintains the same intended use, physical attributes, performance characteristics, and materials as the Mesh GPS™ Deployment Balloon (K092726).

The Introducer Tool that will be packaged with all size configurations of the proposed device is the same as the Introducer Tool currently provided in the predicate Composix™ L/P Mesh device, as cleared in K061754.

Performance Data:

Biocompatibility testing in accordance to ISO 10993-1 standards was conducted on the proposed device (mesh and positioning system) and the results indicate that the device is biocompatible per these standards.

No biocompatibility testing was conducted on the Introducer Tool to be packaged with the proposed device as the 304 Stainless Steel material used for the rolling tines is a recognized biocompatible material as per ASTM F899 - 09e1 Standard Specification for Wrought Stainless Steels for Surgical Instruments. In addition, the polymer handle attached to the rolling tines and the T-cap are non patient contacting material, and therefore, not subject to biocompatibility testing requirements.

Bench testing results and in vivo simulated use experiments demonstrate that the proposed device design meets product specifications and intended uses.

All test results provided in this submission support the safety and effectiveness of the device for its intended use and demonstrate that the proposed device is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 16 2010

C. R. Bard, Inc.
Davol, Inc.
% Keti Sino
100 Crossing Boulevard
Warwick, Rhode Island 02886

Re: K102766
Trade/Device Name: Composix™ L/P Mesh with Echo PS™ Positioning System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL, OQL, GCJ
Dated: September 23, 2010
Received: September 24, 2010

Dear Keti Sino:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K102766

INDICATION FOR USE STATEMENT

510(k) Number (if known):

Device Name: **Composix™ L/P Mesh with Echo PS™ Positioning System**

Composix™ L/P Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. The Echo PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prosthetics during laparoscopic hernia repair.

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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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