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NOV 2 2012

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary is provided per the requirements of section 807.92(c). The information listed below applies to and is identical for both devices being modified as part of this bundled submission.

Submitter Information:

Submitter's Name:	Davol, Inc., Subsidiary of C. R. Bard, Inc.
Contact Person:	Keti Sino Regulatory Affairs Specialist
Address:	100 Crossings Boulevard Warwick, RI 02886
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Email:	Keti.Sino@crbard.com

Device Name:

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

Predicate Device Names:

- Ventralight™ ST Mesh with Echo PS™ Positioning System, K110820 (Davol Inc.), FDA cleared on 04/01/2011
- Composix™ L/P Mesh with Echo PS™ Positioning System, K102766 (Davol Inc.), FDA cleared on 12/16/2010

Device Descriptions:

The proposed Ventralight™ ST Mesh with Echo PS™ Positioning System and Composix™ L/P Mesh with Echo PS™ Positioning System devices both comprise of a hernia repair mesh with a pre-attached mesh positioning system (mesh deployment balloon). A brief description of the two (2) mesh components is as follows:

- The Ventralight™ ST Mesh is a low profile, sterile, single use device indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias. This device is co-knitted using polypropylene (PP) and polyglycolic acid (PGA) fibers to result in a two-sided mesh with a PP surface and a PGA surface. The mesh is coated on the PGA surface with a bioresorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel that is resorbed from the site in less than 30 days.
- The Composix™ L/P Mesh is a low profile, nonabsorbable, sterile prosthesis indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. It is constructed of one layer of large pore polypropylene mesh and one layer of expanded polytetrafluoroethylene (ePTFE) stitched together with PTFE monofilament.

Each of the meshes described above will be sold pre-attached to the Echo PS™ Positioning System. The positioning system is composed of a nylon balloon that is pre-attached to the mesh via use of polycarbonate connectors, and is designed to help facilitate laparoscopic deployment, including unrolling, positioning, and placement of the prostheses.

Both of the proposed devices will also include an Introducer Tool and inflation assembly accessory designed to aid the user in laparoscopic introduction and inflation of the mesh/positioning system assembly. Both of these accessories in the proposed device are identical to those cleared via K110820 and K102766.

Intended Uses:

- The Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias. The Echo PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prosthetics during laparoscopic hernia repair.
- 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 Uses:

The Ventralight™ ST Mesh with Echo PS™ Positioning System has the same indication: reconstruction of soft tissues deficiencies such as the repair of hernias as well as to facilitate the delivery of soft tissue prosthetics during laparoscopic hernia repair. Further, the proposed product has the same physical attributes and performance characteristics as the predicate device.

The Composix™ L/P Mesh with Echo PS™ Positioning System has the same indication: reconstruction of soft tissues deficiencies such as the repair of hernias as well as to facilitate the delivery of soft tissue prosthetics during laparoscopic hernia repair. Further, the proposed product has the same physical attributes and performance characteristics as the predicate device.

The Introducer Tool and inflation assembly accessories to be included with either mesh configuration also maintain the same intended uses as their cleared predicates.

The change described in this submission is a modification solely to the design of the Echo PS™ Positioning System which is sold pre-attached to both meshes and is identical in both products, with no change to either of the permanently implantable mesh components or related accessories included with the device.

The inflation tube component of the positioning system will be modified to include an anchor which will improve the connection between the tube and associated inflation assembly. This same inflation tube component of the positioning system is also being modified to include white markings which more clearly identify the cutting point of the tube to the user.

Performance Data:

Biocompatibility testing in accordance with ISO 10993-1 standards was conducted to assess the design modification on the proposed Ventralight™ ST Mesh with Echo PS™ Positioning System and Composix™ L/P Mesh with Echo PS™ Positioning System and the results indicate that the devices are biocompatible per these standards.

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 Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 2, 2012

C.R. Bard, Incorporated
% Ms. Keti Sino
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K122436
Trade Name: Ventralight™ ST Mesh with Echo PS™ Positioning System, Composix™ L/P Mesh with Echo PS™ Positioning System
Regulation Number: 21 CFR 878.3300, 21 CFR 878.1500
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL, OQL, GCJ
Dated: October 05, 2012
Received: October 09, 2012

Dear Ms. 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

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

Enclosure

INDICATION FOR USE STATEMENT

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

Device Name: **Ventralight™ ST Mesh with Echo PS™ Positioning System**

Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias. 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)

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

510(k) Number K122436

INDICATION FOR USE STATEMENT

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

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

510(k) Number K122436