K110820 Page 1/3

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

APR - 1 2011

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

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
Telephone:	(401) 825-8575
Fax:	(401) 825-8763
Email:	Keti.sino@crbard.com

Device Name:

Trade Name:	Ventralight™ ST 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
Subsequent Codes:	- Class II, § 878.3300, Product Code OQL - Class II, § 876.1500, Product Code GCJ

Predicate Device Names:

- Ventralight™ ST Mesh, K101851 (Davol Inc.), FDA cleared on 07/15/2010
- Composix™ L/P Mesh with Echo PS™ Positioning System, K102766 (Davol Inc.), FDA cleared on 12/16/2010

Device Description:

The proposed Ventralight™ ST Mesh with Echo PS™ Positioning System is comprised of a hernia repair mesh with a pre-attached mesh positioning system (mesh deployment balloon). All sizes of the proposed product with the exception of the largest size will also include an Introducer Tool designed to aid the user in laparoscopic introduction of the mesh/positioning system assembly.

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. The fascial side of the mesh allows a prompt fibroblastic response through the interstices of the mesh, allowing for complete tissue ingrowth, similar to polypropylene mesh alone. The visceral side of the mesh is a bioresorbable coating, separating the mesh from underlying tissue and organ surfaces to minimize tissue attachment to the mesh. Shortly after placement, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days.

The Ventralight™ ST Mesh described above will be packaged preassembled with the Echo PS™ Positioning System, a removable mesh deployment balloon, previously cleared under K102766. The positioning system is an RF welded nylon balloon that is pre-attached to the mesh via the use of polycarbonate connectors, and is designed to help facilitate laparoscopic deployment, including unrolling, positioning, and placement of the Ventralight™ ST Mesh. The positioning system is inflated via use of the included inflation assembly, which is also identical to that cleared with the predicate positioning system under K102766.

For user convenience, all sizes of the proposed product with the exception of the largest size also include an Introducer Tool which is intended to facilitate delivery to the operative site. The largest configuration of the proposed product, the 12" x 14" size does not include an Introducer Tool as this size is recommended for deployment directly through a trocar incision site. The Introducer Tool included with the proposed product is identical to the Introducer Tool cleared under K102766 which consists of a handle with a thin stainless steel rod and a T-cap. The device is split into two pieces along the length of the entire rod and attached on one end to the handle.

Intended Use:

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.

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

The Ventralight™ ST Mesh and the predicate mesh have the same indication: reconstruction of soft tissues deficiencies such as the repair of hernias. Further, the proposed product has the same intended use, physical attributes, and performance characteristics, as the predicate Ventralight™ ST Mesh.

The Echo PS™ Positioning System maintains the same intended use, physical attributes, and performance characteristics, as the cleared Echo PS™ Positioning System (K102766). Further, the included inflation assembly intended to be used for the purposes of inflating the positioning system is also identical to the inflation assembly cleared under K102766.

The proposed product will combine into one the currently marketed Ventralight™ ST Mesh cleared under K101851, preassembled with the currently marketed Echo PS™ Positioning System cleared as part of K102766. The proposed product will also include an Introducer Tool and inflation assembly, both identical to those previously cleared as part of the positioning system predicate (K102766).

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 is non patient contacting, 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

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

APR - 1 2011

Re: K110820 .
Trade/Device Name: Ventralight™ ST 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: March 22, 2011
Received: March 23, 2011

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.

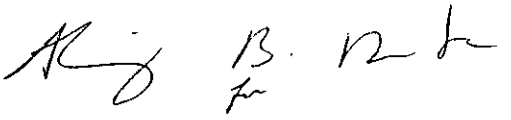
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K110820

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)

David Krause for MKM

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

510(k) Number K110820