K130968
Page 1/3

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 0 1 2013

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.
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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 with Echo PS ™ Positioning System, K122436 (Davol Inc.), FDA cleared on 11/02/2012

Device Description:

The proposed Ventralight™ ST Mesh with Echo PS™ Positioning System is comprised of a permanently implantable mesh with a pre-attached disposable mesh positioning system (mesh deployment balloon). All product sizes include an inflation assembly to be used with the mesh positioning system and some will also include an Introducer Tool designed to aid the user in laparoscopic introduction of the entire mesh/positioning system assembly.

The Ventralight™ ST Mesh is a low profile, sterile, single use device 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 to be used with the proposed device is identical to that cleared via K122436.

The Ventralight™ ST Mesh described above will be packaged preassembled with the Echo PS™ Positioning System, a removable mesh deployment balloon that is pre-attached to the mesh and is designed to help facilitate laparoscopic deployment, including unrolling, positioning, and placement. 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 K122436.

For user convenience, specific sizes of the proposed product will also include an Introducer Tool which is intended to facilitate delivery to the operative site. The Introducer Tool included with the proposed product is identical to the Introducer Tool cleared under K122436 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 to be utilized with Echo PS™ Positioning System for the proposed device has the same indications for use and performance characteristics as the mesh cleared via the predicate K122436.

The proposed Echo PS™ Positioning System maintains the same intended use and performance characteristics as the Echo PS™ Positioning System cleared via the predicate K122436.

The proposed modification to the device is a line extension to offer four (4) additional sizes of Ventralight ST™ Mesh with Echo PS™ Positioning System. The new codes will also include an Introducer Tool (where applicable) and inflation assembly, both identical to those previously cleared under the predicate K122436.

Performance Data:

Biocompatibility testing previously conducted (as presented via K122436) is also applicable to the proposed device and thus will not be repeated. All testing conducted to date (as per the requirements of ISO 10993) indicate that the device is biocompatible as per its intended use.

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.

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

May 1, 2013

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

Re: K130968
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: April 05, 2013
Received: April 08, 2013

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, FOR

Peter D. Rumm -S

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

Enclosure

Indications for Use

510(k) Number (if known): K130968

Device Name: **Ventralight™ STMesh with Echo PS™ Positioning System**

Indications For Use: 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___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

(Division Sign-Off)
Division of Surgical Devices
510(k) Number:K130968