510(k) SUMMARY

K101851

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

JUL 15 2010

510(k) Number:	TBD
Owner Name:	Davol Inc., Subsidiary of C. R. Bard, Inc.
Address:	100 Crossings Boulevard Warwick, RI 02886
Contact Person:	Michelle Godin Sr. Regulatory Affairs Associate Tel: 401-825-8589 Fax: 401-825-8765 Email address: michelle.godin@crbard.com
Alternate Contact:	Thomas Hutchinson Vice President, Regulatory and Clinical Affairs Tel: 401-825-8409 Fax: 401-825-8765 Email address: tom.hutchinson@crbard.com
Date Prepared:	June 30, 2010
Device Trade Name:	Ventralight ST Mesh
Device Common Name:	Surgical Mesh
Class:	Class II, 21 CFR 878.3300, Product Code FTL

Predicate Device(s):

- Sepramesh IP Bioresorbable Coating/Permanent Mesh (K040868, K053066, K063739)

Device Description:

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, encouraging 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.

Indication for Use:

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

Comparison to Predicate Devices:

The Ventralight ST Mesh has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the Ventralight ST Mesh are the same as the predicate device including packaging, biocompatibility, sterilization, and labeling. The technological characteristics include a co-knitted PGA and polypropylene mesh layer to allow for tissue in-growth and a bioresorbable coating to minimize tissue attachment. The only difference between the predicate device and the proposed device is that the proposed device, Ventralight ST Mesh, is a low profile version of the predicate device, Sepramesh IP Mesh. By creating a low profile version of Sepramesh IP Mesh, minimum trocar sizes can be utilized for deployment of the mesh in laparoscopic ventral hernia repairs. To create a low profile version of Sepramesh IP Mesh, two minor modifications were required. The first modification is that the polypropylene mesh layer is now constructed of a lighter weight polypropylene monofilament which is identical in the polypropylene material composition and knit pattern and differs in diameter only by .001 in. The second modification is in the PGA layer. Additional PGA was added to fill in the interlayer spaces on the top layer to pull the co-knitted PP/PGA mesh tighter to the top layer PGA fibers and the bioresorbable

coating. The overall knitting process remains the same. Where minor technological differences exist between the proposed device and the predicate device, performance testing demonstrates that these differences do not adversely affect the safety and effectiveness of the proposed device.

Summary of Non-Clinical Testing:

Bench testing and animal studies were performed on the Ventralight ST Mesh to support substantial equivalence. Bench testing on the proposed device included PGA pullout strength testing, burst strength testing, tear strength testing, suture retention strength testing, dry bond strength testing, and hydrogel disruption testing after laparoscopic deployment. Predicate device testing included seal strength testing, package qualification testing, and biocompatibility testing as there were no packaging or material changes to the device. A 4 week post-implantation study in a porcine model was completed on the predicate device and proposed device to evaluate tissue attachment, mesh contracture, tissue in-growth, and host inflammatory and fibrotic response for both devices. Results of testing demonstrate that the Ventralight ST Mesh design meets product specifications and intended uses.

Statement of Equivalence:

The Ventralight ST Mesh has the same indications for use and technological characteristics as the predicate device. Based on this and the design and engineering data provided in the Premarket Notification, the proposed Ventralight ST Mesh has been shown to be substantially equivalent to the cleared Sepramesh IP Mesh.

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

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

JUL 15 2010

Re: K101851
Trade/Device Name: Ventralight ST Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 30, 2010
Received: July 1, 2010

Dear Ms. Godin:

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

Indications for Use

JUL 15 2010

510(k) Number (if known): K101851

Device Name: Ventralight ST Mesh

The Ventralight ST Mesh is intended for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

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)

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

510(k) Number K101851