DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Davol Incorporated, Subsidiary of C. R. Bard Incorporated
Mr. Andrew Harrell
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

September 18, 2015

Re: K143743
Trade/Device Name: ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL, ORQ, GCJ
Dated: August 14, 2015
Received: August 17, 2015

Dear Mr. Harrell:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143743

Device Name

ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh

Indications for Use *(Describe)*

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

The ECHO 2.0™ Lap System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

This 510(k) Summary has been prepared per the requirements of Section 21 CFR 807.92 on September 17th, 2015.

I. Submitter

Submitter's Name:	Davol, Inc., Subsidiary of C. R. Bard, Inc.
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II. Device

Trade Name:	ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh
Common/Usual Name:	Surgical Mesh; Mesh, Surgical, Deployer; Laparoscope, General & Plastic Surgery;
Classification Name:	Mesh, Surgical, Polymeric & Deployer
Product Classification:	Class II, § 878.3300, Product Code FTL Class II, § 878.3300, Product Code ORQ Class II, § 876.1500, Product Code GCJ

III. Predicate Devices

- Bard® VENTRALIGHT™ ST Mesh with Echo PS™ Positioning System (Primary Predicate)
  - K110820 (Davol, Inc.), FDA cleared on 04/01/2011
  - K122436 (Davol, Inc.), FDA cleared on 11/02/2012
  - K130968 (Davol, Inc.), FDA cleared on 05/01/2013
- Minnesota Medical Development, Inc. (MMDI) REBOUND HRD V™ Hernia Mesh Device
  - K083467 (MMDI), FDA cleared on 04/23/2009

IV. Reference Device

- Genzyme Biosurgery COTTONY II Polyester Nonabsorbable Surgical Suture

- K021019 (Genzyme Corporation.), FDA cleared on 06/18/2002

V. Device Description

The proposed ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh is a low profile, bioresorbable, coated, permanent mesh, with a pre-attached removable positioning system, designed for the reconstruction of soft tissue deficiencies during laparoscopic ventral hernia repair.

VENTRALIGHT™ ST Mesh is a dual-component (absorbable and nonabsorbable) sterile prosthesis designed for the reconstruction of soft tissue deficiencies. The low profile mesh facilitates laparoscopic deployment and the pre-sized shapes offer ready-to-use benefits. VENTRALIGHT™ ST Mesh 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 uncoated fascial side of the mesh allows for 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 that separates the mesh from underlying tissue and visceral organ surfaces to minimize tissue attachment to the mesh. Shortly after hydration, 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 pre-assembled to the ECHO 2.0™ Lap System. The ECHO 2.0™ Lap System is made of a deployment frame (pre-shaped nitinol wire encased in a thermoplastic coated nylon sleeve with a center hoisting loop) which is pre-attached to the VENTRALIGHT™ ST Mesh with connectors. Once inserted, the deployment frame facilitates laparoscopic deployment without the need of ancillary devices. Once initial mesh fixation is complete, the ECHO 2.0™ Lap System is completely removed from the body by cutting the center hoisting loop at the patient's skin level and pulling the deployment frame off the mesh and directly out of the abdominal cavity through a 10mm (or larger) trocar.

VI. 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 2.0™ Lap System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.

VII. Comparison of Technological Characteristics with the Predicate Devices

The proposed VENTRALIGHT™ ST Mesh with ECHO 2.0™ Lap System has the same intended use as the primary predicate device Bard® VENTRALIGHT™ ST Mesh with Echo PS™ Positioning System and a similar intended use as the REBOUND HRD V™ Hernia Mesh predicate device. Additionally, all devices (proposed and predicates) are intended for use in the reconstruction/reinforcement of soft tissue deficiencies.

The Ventralight™ ST Mesh utilized for the proposed device is identical to the primary predicate device Bard® VENTRALIGHT™ ST Mesh with Echo PS™ Positioning System and has the same indication for use, physical attributes, and performance characteristics.

In regards to the deployment frame, both the proposed device and the primary predicate utilize the same nylon mesh connectors and similar nylon polyurethane material. The density and color of the nylon polyurethane material slightly differ between the proposed product and primary predicate. The proposed product utilizes smaller denier white nylon polyurethane with larger denier green nylon polyurethane "discs" at the mesh connector location unlike the primary predicate which only utilizes the larger denier green nylon polyurethane without discs for the deployment frame.

The proposed device and the primary predicate's deployment frame feature a pre-attached mechanism to aid in positioning the device over the center of the defect, however the materials used differ. To aid in centering the device, the primary predicate utilizes a pellethane inflation tube with a tecothane needle loop complex, however the proposed product utilizes a commercially available uncoated non-absorbable poly(ethylene) surgical suture.

The proposed device and the predicate REBOUND HRD V™ Hernia Mesh device utilize a nitinol material for the deployment frame, however the method of nitinol attachment differ. The REBOUND HRD V™ Hernia Mesh Device connects the ends of the nitinol material via a welding process, however the proposed device attaches the nitinol ends using a stainless steel crimp. Additionally, the nitinol deployment frame included with the REBOUND HRD V™ Hernia Mesh device is intended to be a part of the permanent mesh implant; however the nitinol deployment frame included with the proposed device has the same limited patient contact exposure as the primary predicate deployment frame.

VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

VENTRALIGHT™ ST Mesh is considered a tissue-contacting, permanent implant. Therefore, the following tests are required and were leveraged from the primary predicate device (Bard® VENTRALIGHT™ ST Mesh with Echo PS™ Positioning System) in support of this premarket notification:

- Cytotoxicity
- Sensitization
- Genotoxicity
- Irritation
- Pyrogenicity
- Hemolysis
- Local Effects

- Acute Toxicity
- Subchronic Toxicity

The tissue contacting materials in the ECHO 2.0™ Lap System (comprised of the mesh connectors, center hoisting loop and deployment frame) are categorized as externally communicating with tissue/bone/dentin contact for limited duration (<24hr). Therefore, the following tests are required:

- Cytotoxicity
- Sensitization
- Intracutaneous Injection
- Systemic Injection

Electrical safety and electromagnetic compatibility (EMC)
There are no electrical or metal components in the proposed ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh; therefore the proposed device does not require EMC and Electrical Safety evaluation.

Software Verification and Validation Testing
The proposed ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh does not contain software.

Performance Testing - Bench
The following physical and performance characteristics were measured to compare the proposed ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh to the primary predicate VENTRALIGHT™ ST Mesh with Echo PS™ Positioning System:

- Bench-Top Simulated Use
- Mesh Integrity (following simulated use)
- Ball Burst
- Connector to Mesh Attachment Strength
- Connector to Deployment Frame Attachment Strength

Performance Testing - Mechanical
Additionally, the following physical characteristics were measured to demonstrate that the proposed ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh performs as intended:

- Nylon Peel Strength
- Center Hoisting Loop to Deployment Frame Attachment Strength
- Crimp Integrity

Performance Testing – Porcine Animal Model
Simulated use testing was conducted in a porcine animal model to evaluate the utility of the proposed ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh. Evaluations were conducted via use of surveys which captured surgeon feedback on product performance.

Clinical Study
No clinical study was required in support of the proposed ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh.

IX. Conclusions

The test results provided in this submission demonstrate that the device is substantially equivalent to its predicates.