DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 1, 2017

C.R. Bard
Ms. Christine Lloyd
Senior Regulatory Affairs Specialist
100 Crossing Blvd.
Warwick, Rhode Island 02886

Re: K170294
Trade/Device Name: Ventralight St Mesh With Echo 2 Positioning System 11cm (4.5") Circle, Ventralight St Mesh With Echo 2 Positioning System 10cm X 15cm (4"x 6") Ellipse, Ventralight St Mesh With Echo 2 Positioning System 15cm (6") Circle, Ventralight St Mesh With Echo 2 Positioning System 15cm X 20cm (6"x8") Ellipse, Ventralight St Mesh With Echo 2 Positioning System 15cm X 25cm (6"x10") Oval
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL, ORQ, GCJ
Dated: January 30, 2017
Received: January 31, 2017

Dear Ms. Lloyd:

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" (21 CFR 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,

David Krause -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)*
K170294

Device Name

VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System

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™ Positioning System is intended to facilitate the delivery and positioning 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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I. SUBMITTER

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Date Prepared: January 30, 2017

II. DEVICE

Name of Device:	VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System Product Reference Numbers: 5990011, 5991015, 5990015, 5991520, 5991525, 5991823, 5990020, 5992025, 5992533, and 5993035
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	class II
Product Code:	FTL, ORQ, GCJ

III. PREDICATE DEVICE

The Predicate Device for this submission is the ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh cleared via 510(k) K143743 by Davol Inc. This Predicate has not been subject to a design-related recall.

The Reference Device for this submission, the VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System was cleared for use via 510(k) K130968 and is marketed by Davol Inc. This Reference Device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Subject Device, VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System is provided sterile for single use and consists of an implantable surgical mesh (VENTRALIGHT™ ST Mesh) with a

pre-attached mesh positioning system (ECHO 2™ Positioning System). The Subject Device is designed for the reconstruction of soft tissue deficiencies during laparoscopic ventral hernia repair.

Device Accessories

The Mesh Introducer tool (Subject Device accessory) will be distributed with several configurations of the Subject Device. The Mesh Introducer tool assists in rolling and introducing the Subject Device into the trocar. The Predicate Device did not include a Mesh Introducer tool. However the Reference Device, the VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System (K130968), includes the Mesh Introducer tool.

V. 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™ Positioning System is intended to facilitate the delivery and positioning of soft tissue prostheses during laparoscopic hernia repair.

The Indications for Use statement for the Subject Device is similar to the Predicate Device. The Subject, Predicate and Reference Devices all have the same intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject Device, the VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System has the same intended use and technological characteristics with regard to design, materials, and sterilization as the Predicate Device, ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh (K143743). The Devices (Subject and Predicate) are intended for use in the reconstruction/reinforcement of soft tissue deficiencies and utilize a deployment system to support the permanent implantable mesh during positioning and placement. Both the Subject Device and the Predicate feature a mechanism to aid in positioning the device over the center of the defect, the Positioning System.

The Subject Device includes the identical VENTRALIGHT™ ST Mesh as the Predicate Device, ECHO 2.0™ Lap System with VENTRALIGHT™ ST Mesh.

Both the Subject Device and Predicate utilize a Deployment Frame to facilitate the delivery and positioning of soft tissue prostheses during laparoscopic hernia repair, however the Deployment Frames differ. The Subject Deployment Frame has been redesigned to separate into one strand for easier removal by the clinician. The Deployment Frame continues to contain a Nitinol wire encased within a welded nylon frame. A suture continues to be attached to nylon supports and is located at the center of the Deployment Frame. Mesh Connectors continue to be utilized to attach the Deployment Frame to the Ventralight ST™ Mesh.

The Predicate Device did not include a Mesh Introducer tool. However the Reference Device, the VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System (K130968), includes the Mesh Introducer tool.

The Subject, Predicate and Reference Devices utilize similar packaging materials, are manufactured in the same facility, use the same manufacturing processes, use the same sterilization facility and are sterilized in the same EtO cycle.

Refer to Table 5-1 for an overview of the general characteristics related to substantial equivalence.

Table 5-1: Device Substantial Equivalence – General Characteristics

Device Features	Subject Device	Predicate Device K143743
Intended Use	Same as Predicate Device	The ECHO 2.0™ Lap System is intended to help facilitate laparoscopic deployment of the VENTRALIGHT™ ST Mesh.
Indication for Use (Mesh)	Same as Predicate Device	VENTRALIGHT™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.
Indication for Use (Positioning System)	The Subject Device includes "… delivery and positioning of …" which is similar to the Predicate Device The ECHO 2™ Positioning System is intended to facilitate the delivery *and positioning* of the soft tissue prostheses during laparoscopic hernia repair.	The ECHO 2.0™ Lap System is intended to facilitate the delivery of the soft tissue prostheses during laparoscopic hernia repair.
Device Sterilization	Same as Predicate Device	EtO

VII. PERFORMANCE DATA

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

Performance standards

No performance standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Biocompatibility testing

The biocompatibility evaluation for the VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System was conducted in accordance with Guidance for Industry and Food and Drug Administration Staff Use of International Standard ISO 10993-1, "*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*" June 16, 2016, 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.

THE VENTRALIGHT ™ ST Mesh and the Mesh Introducer tool are identical to the devices cleared via K143743 and K130968 respectively therefore, the tests were not repeated.

Biocompatibility testing was required based upon changes to the ECHO 2™ Positioning System. The tissue contacting materials of the Subject Positioning System are categorized as externally communicating with tissue/bone/dentin contact for limited duration (<24hr). The following tests were successfully performed.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity

Electrical safety and electromagnetic compatibility (EMC)

The VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System is not an electro-mechanical medical device nor is it a medical system, therefore this section does not apply.

Software Verification and Validation Testing

The VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System does not contain software; therefore this section does not apply.

Product Testing

The VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System passed all the test requirements and demonstrated substantial equivalence to the test results of the Predicate Device. Performance and functional testing of the VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System included;

- Simulated use evaluations using a bench-top simulator
- Mechanical testing of the VENTRALIGHT™ ST Mesh
- Mechanical testing of the ECHO 2™ Positioning System

All samples tested met the established acceptance criteria.

Cadaveric Study

The safety and feasibility of the VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System was evaluated by human cadaver studies. All samples tested met the established acceptance criteria.

These studies demonstrated that the VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System can safely deliver and support the mesh construct without interfering with mesh fixation or removal of the Deployment Frame. The Subject Device performed similar to that of the Predicate Device.

Clinical Studies

Clinical studies were not performed for the submission of this Subject Device nor were clinical studies performed for the Predicate Device.

VIII. CONCLUSIONS

The Subject Device, VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System maintains the same safety and performance as the Predicate Device. The Subject and Predicate Devices have similar indications, the same intended use, the same technological characteristics, the same principles of operation and product testing provides evidence of performance equivalence. Therefore, the VENTRALIGHT™ ST Mesh with ECHO 2™ Positioning System is substantially equivalent to the Predicate Device.