



March 30, 2020

Deep Blue Medical Advances, Inc.  
% Nancy Lince  
Regulatory Affairs Consultant  
Lince Consulting, LLC  
111 Deerwood Road, Suite 200  
San Ramon, California 95483

Re: K193144

Trade/Device Name: T-Line Hernia Mesh  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: Class II  
Product Code: FTL  
Dated: November 11, 2019  
Received: November 13, 2019

Dear Ms. Lince:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.  
Acting Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K193144

Device Name

T-Line Hernia Mesh

Indications for Use (Describe)

T-LINE™ HERNIA MESH is indicated for the reinforcement of soft tissue where weakness exists for the repair of ventral hernias performed via an open onlay approach.

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**

**DATE PREPARED** November 11, 2019

**SUBMITTER** **Deep Blue Medical Advances, Inc.**  
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**CONTACT PERSON**  
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Lincé Consulting, LLC  
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**DEVICE** T-Line™ Hernia Mesh  
COMMON NAME: Surgical Mesh  
PRODUCT CODE(S): FTL  
CFR CLASSIFICATION AND NAME: 21 CFR§878.3300 Mesh, Surgical, Polymeric

**PREDICATE DEVICE** K052155 Bard Soft Mesh  
Reference Device: K133356 Ethicon, Inc. PROLENE Polypropylene Suture

**DEVICE DESCRIPTION** The T-Line Hernia Mesh is manufactured by knitting and heat pressing standard medical grade polypropylene monofilament yarn using well-established standard processes that are used to manufacture other commercially available hernia meshes. Mesh extensions are used to apply the device to the abdominal wall. The extensions of the T-Line Hernia Mesh are incorporated directly into the mesh body. The mesh design incorporates continuous, uninterrupted, seamless extensions from the mesh body to facilitate mesh securement to tissue. After knitting, needles are swaged onto the ends of the extensions to allow the extensions to be sewn into the abdominal fascia by surgeons akin to how sutures are sewn into fascia.

**INTENDED USE** T-LINE™ HERNIA MESH is indicated for the reinforcement of soft tissue where weakness exists for the repair of ventral hernias performed via an open onlay approach.

**COMPARISON TO PREDICATE TECHNOLOGICAL CHARACTERISTICS** The T-Line Hernia Mesh is substantially equivalent to the Bard Soft Mesh (K052155), which is the primary predicate device. This 510(k) also references the Ethicon, Inc. PROLENE Polypropylene Suture (K133356) to address the technological difference (i.e. extensions versus suture fixation) between the subject and predicate device. The T-Line Hernia Mesh has the same intended use and similar technological characteristics as the predicate surgical mesh device. Specifically, both devices are intended for use in soft tissue reinforcement with similar materials and design characteristics. The characteristics evaluated such as knit, thickness, and filament diameter are within the same ranges. Both devices are designed with a large-pore

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structure to promote bioincorporation of tissue. The primary difference is that the subject device is designed with extensions that are incorporated (sewn) into the fascia to reduce the stresses currently placed on the mesh, tissue, suture interface. The T-Line Hernia Mesh extensions are made from the same polypropylene material as the mesh body and are knit by the loom as part of the mesh knit. The extension surface area is approximately 15 times greater than the surface area of #0 polypropylene suture.

## **PERFORMANCE DATA**

Based on the results of *in vivo* testing, the T-Line Hernia Mesh demonstrated substantially equivalent safety and performance characteristics when compared to the predicate mesh when performing open hernia repair in a simulated use porcine model. There were no biologically significant differences between histologic and gross findings for up to 6 months post-operatively. All animals showed good bioincorporation and there was no evidence of adverse local or systemic effects of either mesh in any animal. The results revealed a normal inflammatory response to the polypropylene meshes.

At 1-, 3-, and 6- month post-operative endpoints, histological evaluation of inflammation, bioincorporation and fibrosis at the T-Line Hernia Mesh and Bard Mesh control sites was conducted and associated cellular populations were scored and compared. Additionally, potential mesh contraction was assessed for both test and control mesh over time. Results showed no biologically significant differences between the T-Line Hernia Mesh and predicate Bard Soft Mesh throughout the duration of the study. No clinical observations, changes in clinical pathology parameters, or changes in body weights were linked to either the test or control meshes during the study. Microscopically, the same tissue reactions were seen with both the T-Line and the Control reference mesh, consisting of both inflammatory and reparative processes. From a biological standpoint, the T-Line and Control Reference mesh samples elicited an equivalent overall tissue response. Finally, there were no differences in mesh stability between the T-Line and Control reference mesh at any time point. Results therefore demonstrated equivalent safety and performance between the T-Line Hernia Mesh and predicate Bard Soft Mesh when surgically implanted into Yucatan pigs for up to 6 months.

Performance specifications for the subject device were derived from a variety of design inputs; including procedural characteristics and requirements, clinical input from physicians, review of predicate device characteristics and labeling, user interface considerations, relevant external standards, and outputs from the company's risk management process. The data showed the T-Line Hernia Mesh functions as intended and does not raise any new issues of safety and effectiveness when compared to the predicate device.

## **CONCLUSION**

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the T-Line Hernia Mesh is substantially equivalent to the currently marketed predicate device.