11/28/2022

Deep Blue Medical Advances, Inc.
℅ Nancy Lincé
President and CEO
Lincé Consulting, LLC
111 Deerwood Road, Suite 200
San Ramon, California 94583

Re: K221556
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: September 9, 2022
Received: September 12, 2022

Dear Nancy Lincé:

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/pmn.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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221556

Device Name
T-Line Hernia Mesh

Indications for Use *(Describe)*
The 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 or sublay approach in adults (greater than 21 years of age).

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.

510(k) SUMMARY

DATE PREPARED September 8, 2022

SUBMITTER

Deep Blue Medical Advances, Inc.
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Durham, NC 27701
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CONTACT PERSON
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DEVICE T-Line® Hernia Mesh
Common Name: Surgical MeshProduct Code(S): FTL
CFR Classification and Name: 21 CFR§878.3300 Mesh, Surgical, Polymeric

PREDICATE DEVICE K193144 T-Line® Hernia Mesh

Reference Devices: K052155 Bard Soft Mesh; 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 incorporatescontinuous, 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 The 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 or sublay approach in adults (greater than 21 years of age).

COMPARISON TO PREDICATE TECHNOLOGICAL CHARACTERISTICS The T-Line® Hernia Mesh is identical to the T-Line® Hernia Mesh cleared under K193144, which is the primary predicate device. The intended use and technological characteristics are identical to the predicate T-Line® Hernia Mesh. This 510(k) was limited to an expansion in the Indications for Use to include an open sublay approach. This 510(k) also references the Bard Soft Mesh (K052155) and the Ethicon, Inc. PROLENE Polypropylene Suture (K133356) which were used as the controls in the

in vivo GLP chronic animal study to support the open sublay approach.

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 control mesh when performing open hernia repair via a sublay approach in a simulated use porcine model. There were no biologically significant differences between histological 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 reference Bard Soft Mesh throughout the duration of the study. No clinical observations, changes in clinical pathology parameters, or changes in bodyweights were linked to either the test or control meshes during the study. Microscopically, the same tissue reactions were seen with both the test and control reference mesh, consisting of both inflammatory and reparative processes. From a biological standpoint, the test and control reference mesh samples elicited an equivalent overall tissue response. Finally, there were no differences in mesh stability between the test and control reference mesh at any time point. Results therefore demonstrated equivalent safety and performance between the T-Line® Hernia Mesh and reference Bard Soft Mesh when surgically implanted via a sublay approach into Yucatan pigs for upto 6 months.

Since the design of the T-Line® Hernia Mesh submitted under K193144 is unchanged, no additional performance testing was required as the test results previously submitted remain applicable to the subject T-Line® Hernia Mesh and demonstrated that the device meets functional, performance, and design requirements as well as safety standards.

CONCLUSION

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate and reference devices, substantial equivalence of the T-Line® Hernia Mesh used via a sublay approach has been demonstrated.