October 18, 2023

Deep Blue Medical Advances, Inc.
% Diana Degregorio
Regulatory Affairs Consultant
Lince Consulting, LLC
111 Deerwood Road
Suite 200
San Ramon, California 94583

Re: K232924
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 19, 2023
Received: September 19, 2023

Dear Diana Degregorio:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.10.18 22:28:45 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232924

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 sub lay 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

DATE PREPARED October 18, 2023

SUBMITTER

Deep Blue Medical Advances, Inc.
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Phone: (919) 914-6039
Establishment Registration No.: 3017492634

CONTACT PERSON
Diana DeGregorio
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

T-Line Hernia Mesh (K230227, K221556, K193144)

Product Code(s):	FTL
CFR Classification and Name:	21 CFR§878.3300 Mesh, Surgical, Polymeric

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

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 substantially equivalent to the T-Line Hernia Mesh cleared under K230227, K221556 and K193144. The subject and predicate devices are identical in terms of intended use, indications for use, function, technology, safety, performance as well as procedural steps and labeling. This 510(k) was limited to the addition of a smaller

size of the T-Line Hernia Mesh based on customer feedback.

PERFORMANCE DATA

A risk analysis was conducted and confirmed there are no new risks associated with the subject T-Line Hernia Mesh. Appropriate evaluations have demonstrated that the modified T-Line Hernia Mesh continues to meet the same pre-determined functional and performance requirements and external standard requirements as the predicate device and do not raise any new questions of safety or effectiveness.

CONCLUSION

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