April 15, 2025

ARK Surgical
% Bosmat Friedman-Cox
Regulatory Consultant
ProMedoss, Inc.
6026 Beech Cove Ln.
Charlotte, North Carolina 28269

Re: K250212
Trade/Device Name: LapBox Power Tissue Containment System
Regulation Number: 21 CFR 884.4050
Regulation Name: Gynecologic Laparoscopic Power Morcellation Containment System
Regulatory Class: II
Product Code: PMU
Dated: January 23, 2025
Received: January 24, 2025

Dear Bosmat Friedman-Cox:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250212

Device Name
LapBox Power Tissue Containment System

Indications for Use *(Describe)*
The LapBox Power Tissue Containment System is intended for use as a multiple instrument port and tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue considered benign, resected during single-port or multi-site laparoscopic surgery during power morcellation and removal. The LapBox is compatible with electromechanical laparoscopic power morcellators that are between 15 mm and 18 mm in shaft outer diameter and 135 mm and 180 mm in shaft working length and which have an external component that allows for the proper orientation of the laparoscope to perform a contained morcellation. When used in women with fibroids, the LapBox Power Tissue Containment System is for women who are pre-menopausal and under age 50.

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 [Traditional 510(k)]
LapBox Power Tissue Containment System
510(k) Number K250212

1 SUBMITTER

Applicant's Name:
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Date Prepared: April 10, 2025

Trade Name:
LapBox Power Tissue Containment System

Classification Code: **Device:** Containment System, Laparoscopic Power Morcellation, With Instrument Port
Product Code: PMU
Regulation No: 884.4050
Class: 2
Review Panel: Obstetrics/Gynecology

2 PREDICATE DEVICE

Primary Predicate:

- PneumoLiner, manufactured by Advanced Surgical Concepts Ltd., K192898; Product Code: PMU. The predicate device has not been subject to a design-related recall.

Reference device:

- LapBox Tissue Containment Removal System, manufactured by ARK Surgical, cleared under K221365; Product Code: GCJ.

3 DEVICE DESCRIPTION

The LapBox Power Tissue Containment System is a single use sterile device. It is comprised of a double wall inflatable polyurethane chamber which is mounted on an insertion shaft and is provided with two port sizes. Once the shaft is inserted to the abdominal cavity, the chamber is deployed and the organ to be morcellated is placed within the chamber. The chamber is then

inflated using an external handpump and the sleeve of the chamber is exteriorized. The selected port is then placed over the sleeve in the incision site and the organ can be morcellated using a power morcellator. Once morcellation is complete, the port is removed, and the chamber is deflated and removed from the patient.

4 INDICATIONS FOR USE

The LapBox Power Tissue Containment System is intended for use as a multiple instrument port and tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue considered benign, resected during single-port or multi-site laparoscopic surgery during power morcellation and removal. The LapBox is compatible with electromechanical laparoscopic power morcellators that are between 15 mm and 18 mm in shaft outer diameter and 135 mm and 180 mm in shaft working length and which have an external component that allows for the proper orientation of the laparoscope to perform a contained morcellation. When used in women with fibroids, the LapBox Power Tissue Containment System is for women who are pre-menopausal and under age 50.

5 SUBSTANTIAL EQUIVALENCE

The subject and predicate devices are both single use tissue bags intended to retrieve and contain specimen during power morcellation.

The following table provides a comparison with the predicate:

Feature	LapBox Power Tissue Containment System	PneumoLiner (K192898)
Reg. Number	884.4050	884.4050
Product Code	PMU	PMU
Indication for Use	The LapBox device is intended for use as a multiple instrument port and tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue considered benign, resected during single-port or multi-site laparoscopic surgery during power morcellation and removal. The LapBox is compatible with electromechanical laparoscopic power morcellators that are between 15 mm and 18 mm in shaft outer diameter and 135 mm and 180 mm in shaft working length and which have an external component that allows for the proper orientation of the laparoscope to perform a contained morcellation. When used in women with fibroids, the LapBox Power Tissue Containment System is for women who are pre-menopausal and under age 50.	The PneumoLiner device is intended for use as a multiple instrument port and tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue, considered benign, resected during single-port or multi- site laparoscopic surgery during power morcellation and removal. When used in women with fibroids, the PneumoLiner is for women who are pre-menopausal and under age 50. The PneumoLiner is compatible with bipolar or electromechanical laparoscopic power morcellators that are between 15mm and 18mm in shaft outer diameter and 135mm and 180mm in shaft working length and which have an external component that allows for the proper orientation of the laparoscope to perform a contained morcellation.

Feature	LapBox Power Tissue Containment System	PneumoLiner (K192898)
Principle of Operation	Inserted through umbilical incision to the abdominal cavity, organ placed in chamber, hand pump is connected, and chamber is inflated, , incision size is increased (if needed), and chamber sleeve is exteriorized, port is placed, power morcellation is performed and at completion chamber is deflated, port is removed and chamber extracted.	Incision is made and retractor is placed over incision; boot assembly placed over retractor; bag inserted through boot assembly; organ placed in bag and the boot assembly removed; bag exteriorized and boot assembly put back in place; bag inflated and organ is morcellated; once morcellation is complete, all instruments including boot assembly are removed, and the bag is removed.
Component allowing tools and morcellator access	Use of either a medium or small size designated port	Boot assembly
Pneumoperitoneum/ insufflation	Pneumoperitoneum is maintained in the abdomen with LapBox during the morcellation procedure	Pneumoperitoneum is maintained inside the PneumoLiner during the procedure
Umbilical incision length	25-30 mm	20-25
Chamber/bag and Port/Guard Materials	TPU (Polyurethane) film, Nylon reinforced fabric and polyurethane port	TPU (Polyurethane) film, Nylon reinforced fabric and polyurethane and plastic port
Wall material thickness (TPU thickness)	80 µm	42 µm
Chamber size	140mm X 320 mm	350mm X 500mm
Chamber/bag pattern	None	Grid
Single use	Yes	Yes
Sterility	EtO	Gamma
Shelf-Life	18 months	36 months

The differences in the indications for use do not represent a new intended use.
The differences in technological characteristics do not raise different questions of safety or effectiveness.

6 SUMMARY OF NON-CLINICAL TESTING

The following non-clinical testing is provided in support of our substantial equivalence claim and to demonstrate compliance with the special controls associated with this device type:

Sterilization and Shelf-Life:

Sterilization validation was performed in accordance with ISO 11135, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

Shelf-life of 18 months was validated on device samples following accelerated aging and simulated transit conditioning. Testing evaluated packaging integrity and device functionality

Biocompatibility:

The biocompatibility evaluation for the LapBox Power Tissue Containment System device was conducted in accordance with the FDA biocompatibility guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued September 2023 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 LapBox is considered an externally communicating device, tissue contacting with limited duration.

The following biocompatibility tests were conducted:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Intracutaneous irritation per ISO 10993-10
- Acute Systemic Toxicity per ISO 10993-11
- Pyrogenicity testing per USP <151>

Testing demonstrated that the device was non cytotoxic, non-sensitizer, non-irritant, not systemically toxic and non-pyrogenic.

Non-Clinical Performance Testing (Bench):

Non-clinical performance testing on LapBox Power Tissue Containment System was conducted in accordance with the FDA guidance document "Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures" issued May 26, 2023. Testing included:

- Bacterial Immersion Test: testing included 32 device samples aged beyond shelf life and previously exposed to simulated use; both positive and negative controls were used. Samples were then disinfected and sterilized prior to immersion. The tested chambers were inflated and immersed to assess for impermeability to Brevundimonas Diminuta. After the Immersion Test the entire volume of the TSB within each chamber was membrane filter plated to enumerate the presence of a single colony forming unit of the bacterial species. The test samples did not show any evidence of growth of Brevundimonas Diminuta. The positive and negative controls performed as intended.
- Dimensional Verification Tests: supplemental test to the one provided in K221365 (*referenced below*); a total of 30 non aged units were tested for the dimensions of the following: proximal handle outer diameter; inner tube inner diameter: outer tube inner diameter; and inflation chamber inner diameter. All samples met the prespecified

acceptance criteria.

- Pressure Relief Valve Testing: a total of 30 aged and 30 non aged pressure relief valves were tested to ensure they would relieve pressure above the set target. All samples met the prespecified acceptance criteria.
- Design and Performance Validation Test: a total of 30 aged and 27 no-aged units were tested by 2 trained surgeons using two different morcellators in a simulator with bovine tongue. All samples passed a dye leak test. Design changes were implemented following this test which were validated in supplemental tests.
- Puncturing Force Comparative Test: testing was conducted on double layers and a single layer of the LapBox chamber material with a variety of morcellator and graspers and compared to the results obtained with the predicate. Testing utilized 72 predicate material samples and 72 aged and 72 non aged LapBox material samples. The results obtained with LapBox supported non-inferiority when compared to the predicate.
- Bond Strength Tests: supplemental test to the one provided in K221365 (*referenced below*); 30 aged units were tested to evaluate the air tube bond connection as well as the handpump assembly. All samples met the prespecified acceptance criteria.
- Burst Pressure Evaluation: supplemental test to the one provided in K221365 (*referenced below*); 10 non-aged units with the modified new air tube were tested. All samples met the prespecified acceptance criteria.
- Inflation Pressure Range: a customized jig was developed to evaluate the pressure range required for the LapBox chamber to maintain its shape when subjected to insufflation. One LapBox unit was used. The testing demonstrated that the chamber will maintain its shape at a pressure below that relieved by the pressure relief valve.
- Comparison Force Test: a customized jig was developed to evaluate and compare the outward force exerted by the LapBox and by the predicate. One predicate and one LapBox were utilized in this test. The results demonstrate that when used in accordance with device labeling, a uniform distribution of force by LapBox does not pose a greater risk of compression on adjacent organs when compared to the predicate.

The following additional bench tests previously submitted under K221365 for the reference device were also considered:

- Corrosion Resistance: 30 units of the 2 different metal components were used; samples underwent double sterilization and 18 months accelerated aging prior to testing. No corrosion was noted on any samples.
- Burst Pressure Evaluation: a total of 30 aged and 30 non-aged units were tested to evaluate the burst pressure of the LapBox chamber. All tested units met the prespecified acceptance criteria.
- Bond Strength Tests: 30 non-aged units and 30 aged units were tested. Tensile strength of the following bonds were assessed: chamber assembly; air tube-chamber connection; delivery system-chamber connection; and the handpump assembly. All samples met the prespecified acceptance criteria.
- Dimensional Verification Tests: a total of 36 non aged units were tested for the dimensions for the following: shaft effective length; inner sleeve height; chamber double wall height; chamber outer diameter; and chamber opening. All samples met the prespecified acceptance criteria.
- Viral Penetration ASTM Method F 1671: 30 material samples that have undergone

accelerated aging equivalent to 12 months were tested. All samples met the prespecified acceptance criteria.

- Maximum organ size testing: 2 aged devices used to evaluate the maximum organ size compatible with the LapBox.

Training Validation and Usability Studies:

Multiple studies were conducted to evaluate the usability of the LapBox System and the training program developed by ARK Surgical.

- An initial usability study was conducted which included 31 physicians of varying levels of experience performing a total of 40 procedures in a simulator with bovine tongue. Following training, participants performed the procedure. No device samples had an observed leakage of dye following use. There were minor device issues noted that were addressed via manufacturing and labeling modifications.
- A supplementary usability study in a simulator was conducted, in which 6 physicians conducted a total of 33 procedures. These units were used in the bacterial immersion testing discussed above. There was no evidence of any device leak.
- Training validation was conducted in a porcine model with bovine tongue. A total of 16 physicians of varying levels of experience completed 32 morcellation procedures. The participants underwent the training and then had a 1 hour break prior to performing the procedure. Following the procedure, device samples were subject to a dye leak test. No samples leaked. Minor issues were noted with respect to adherence to the instructions for use. The training and instructions for use (IFU) were revised to address the noted issues and a follow-up usability study was conducted which included 15 physicians who performed 30 power morcellation procedures in a simulator. This study demonstrated that the revisions made to the training and IFU were effective, ensuring the device's safe and effective use in clinical settings.

Additional Animal Studies:

- Performance Characterization Animal In-Vivo Study (Part 1 and 2): The purpose of these studies was to define the performance characteristics of the LapBox System in a porcine model. The first study utilized one animal and evaluated 3 devices, the second study utilized one animal and evaluated 5 devices.

7 Conformance to Special Controls

LapBox Power Tissue Containment System conforms to the following special controls:

1. The patient-contacting components of the device have been demonstrated to be biocompatible.
2. Device components that are labeled sterile have be validated to a sterility assurance level of 10^{-6}.
3. Performance data support shelf-life by demonstrating continued sterility of the device and sterile components, package integrity, and device functionality over the intended shelf life.

4. Non-clinical performance data demonstrate that the device meets design specifications and performance requirements. The following performance characteristics have been tested.
    a. Demonstration of the device impermeability to tissue, cells and fluids.
    b. Demonstration that the device allows for the insertion/withdrawal of laparoscopic instruments while maintaining pneumoperitoneum.
    c. Demonstration that the containment system provides adequate space to perform morcellation and adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera.
    d. Demonstration that intended laparoscopic instruments and morcellators do not compromise the integrity of the containment system.
    e. Demonstration that intended users can adequately deploy the device, morcellate a specimen without compromising the integrity of the device and remove the device without spillage of contents.
5. Training has been developed and validated to ensure users can follow the instructions for use.
6. Labeling includes:
    - Contraindication for use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
    - Contraindication for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal; or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.
      Note: *The language of this contraindication was revised during the review of the predicate device for clarity. The labeling for the LapBox Power Tissue Containment System is consistent with the predicate device and identifies the contraindication as follows: "Do not use for removal of uterine tissue containing suspected fibroids in patients who are: post- menopausal or over 50 years of age; or candidates for en-bloc tissue removal through the vagina or via a mini-laparotomy incision."*
    - The following boxed warning: "Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk."
    - Statement limiting use of device to physicians who have completed the training program.
    - An expiration date or shelf life.

8 CONCLUSION

The LapBox Power Tissue Containment System's performance testing support the substantial equivalence determination as well as compliance with the special controls. The LapBox Power Tissue Containment System is as safe and effective as the predicate device.