August 25, 2022

ARK Surgical, Ltd.
℅ Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K221365
Trade/Device Name: LapBox Tissue Containment Removal System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 29, 2022
Received: July 29, 2022

Dear Bosmat Friedman:

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,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
LapBox Tissue Containment Removal System

Indications for Use *(Describe)*
The LapBox Tissue Containment Removal System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation.

Contraindications: The LapBox Tissue Containment Removal System is contraindicated for laparoscopic power morcellation during gynecologic procedures.
The LapBox Containment Removal System is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

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

[as required by section 807.92(c)]

LapBox Tissue Containment Removal System

510(k) Number K221365

5.1 SUBMITTER

Applicant's Name:
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Charlotte, NC 28269
Phone: 980-308-1636
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Date Prepared:
July 29, 2022

5.2 DEVICE

Trade Name:
LapBox Tissue Containment Removal System

Classification Code:	**Device:**	Laparoscope, General & Plastic Surgery
	Product Code:	GCJ
	Regulation No:	876.1500
	Class:	2
	Medical Specialty:	Gastroenterology/Urology
	Review Panel:	General & Plastic Surgery

5.3 PREDICATE DEVICE

Primary predicate device:

- Tissue Containment System; 10, 14, 17, 25, manufactured by Applied Medical Resources, cleared under K142427; Product Code: GCJ.

5.4 DEVICE DESCRIPTION

The LapBox Tissue Containment Removal 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 manually morcellated. Once morcellation is complete, the port is removed, and the chamber is deflated and removed from the patient.

5.5 INDICATIONS FOR USE

The LapBox Tissue Containment Removal System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation.

Contraindications: The LapBox Tissue Containment Removal System is contraindicated for laparoscopic power morcellation during gynecologic procedures. The LapBox Tissue Containment Removal System is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

5.6 SUBSTANTIAL EQUIVALENCE

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

The following table provides a comparison with the predicate:

Feature	LapBox Tissue Containment Removal System	Tissue Containment System (K142427)	Comparison to Primary Predicate
Reg. Number	876.1500	876.1500	Same
Product Code	GCJ	GCJ	Same
Indication for Use	The LapBox Tissue Containment Removal System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation. Contraindications: The LapBox Tissue Containment Removal System is contraindicated for laparoscopic power morcellation during gynecologic procedures. The LapBox Tissue Containment Removal System is contraindicated for use with	The Applied Medical Tissue Containment System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation. Contraindications: The Tissue Containment System is contraindicated for laparoscopic power morcellation during gynecologic procedures. The Tissue Containment System is contraindicated for use with powered	Same

Feature	LapBox Tissue Containment Removal System	Tissue Containment System (K142427)	Comparison to Primary Predicate
	powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.	cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient	
Principle of Operation	Inserted through umbilical incision to the abdominal cavity, hand pump is connected and chamber is inflated, organ placed in chamber, incision size is increased and chamber sleeve is exteriorized, port is placed, manual morcellation is performed and at completion port is removed, and chamber is deflated and removed.	Folded and inserted through umbilical incision to the abdominal cavity, organ placed in bag, bag opening is exteriorized, bag rim folded until organ reaches the surface and Guard is placed, manual morcellation is performed and at completion Guard and bag are removed.	Similar; The performance of the LapBox System was evaluated via bench and usability testing, the results of which support our substantial equivalency claim
Chamber/bag and Port/Guard Materials	TPU (Polyurethane) film, Nylon reinforced fabric and polyurethane port	TPU (Polyurethane) and coiled HDPE port	Similar
Biocompatibility	The chamber was tested for Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Pyrogenicity and Infrared Spectroscopy. All tests successfully passed.	Per 510(k) summary, the device was tested for Cytotoxicity, Irritation and Sensitization	Same
Single use	Yes	Yes	Same
Sterility	EtO	EtO	Same
Mechanical Properties			
Puncture Force chamber/Bag	Tested against predicate	Tested against predicate	LapBox yielded superior results
Puncture Force Port/Guard	Tested against predicate	Tested against predicate	LapBox yielded superior results
Viral Penetration per ASTM F 1671	Pass	Pass	Same

Any differences in technological characteristics do not raise different questions of safety or effectiveness.

5.7 PERFORMANCE DATA

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

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 testing was performed to evaluate package integrity and device functionality following artificial aging and simulated transit conditioning.

Biocompatibility:

The following biocompatibility tests were performed on the LapBox Tissue Containment Removal System:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Infrared Spectroscopy

Non-Clinical Performance Testing:

The LapBox Tissue Containment Removal System has undergone and successfully passed the following tests:

- Performance Characterization In-Vivo Study
- Corrosion Resistance
- Pressure Relief Valve Testing
- Burst Pressure Evaluation
- Puncturing Force Comparative Test
- Bond Strength Test
- Dimensional Verification Test
- Closure Integrity Test: Bubble Test
- Viral Penetration ASTM Method F 1671
- Design and Performance Validation Test
- Clinical Simulation Study
- Training Validation Study
- Maximum organ size testing

5.8 CONCLUSION

The LapBox Tissue Containment Removal System has the same indications for use as its predicate, the Tissue Containment System. The main technological difference between the LapBox Tissue Containment Removal System and the predicate have been evaluated through extensive bench testing coupled with usability testing. The company has provided sufficient comparative testing between the LapBox Tissue

Containment Removal System and the predicate, Manual Morcellation Containment as well as additional pre-clinical bench and usability data to demonstrate our substantial equivalency claim. Consequently, it is clear that the LapBox Tissue Containment Removal System is as safe and effective as its primary predicate without raising any new safety and/or effectiveness concerns.