

**DE NOVO CLASSIFICATION REQUEST FOR
PNEUMOLINER**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Gynecologic Laparoscopic Power Morcellation Containment System: A gynecologic laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign gynecologic tissue that is not suspected to contain malignancy.

NEW REGULATION NUMBER: 21 CFR 884.4050

CLASSIFICATION: II

PRODUCT CODE: PMU

BACKGROUND

DEVICE NAME: PNEUMOLINER

SUBMISSION NUMBER: DEN150028

DATE OF DE NOVO: JUNE 19, 2015

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REQUESTER'S RECOMMENDED CLASSIFICATION: II

INDICATIONS FOR USE

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. The PneumoLiner is compatible with bipolar or 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.

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109.

Contraindications

- Do not use on tissue that is known or suspected to contain malignancy.
- Do not use 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.
- Do not use in women with undiagnosed uterine bleeding.
- Do not use this device on patients with known or suspected allergies to polyurethane.
- Do not use where the abdominal wall thickness is larger than 10 cm.

Boxed 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.

Warnings

- Do not cut, puncture or scrape the PneumoLiner with the morcellator tip or tenaculum/grasper.
- Check for and remove adhesions that may inhibit proper placement of the device
- At all times prior to morcellating, make sure the tenaculum/grasper is within view when grasping tissue, to prevent it contacting the PneumoLiner.
- The tip of the morcellator must be brought into view, prior to and during each activation to provide confirmation of the position of the morcellator tip and its proximity to the PneumoLiner.
- Do not bring the morcellator tip into contact with the PneumoLiner.
- To prevent risk of contamination, do not re-attach the Boot following removal of the PneumoLiner.
- Any abdominal incision introduces a risk of abdominal hernia
- The PneumoLiner must be fully inflated (12 – 15 mmHg) to minimize the risk of damage to the bag and adjacent organs during morcellation.
- With the tip of the morcellator in view, prior to activating the morcellator, confirm that the tissue specimen is centered within the PneumoLiner.

Precautions

- Device should only be used with 5 mm laparoscopes with $\geq 30^\circ$ lens angle or deflectable tip
- Only use an atraumatic grasper to manipulate the PneumoLiner

- Regarding the grasper/tenaculum used, teeth which are curved proximally to shield their sharp tips may help reduce the risk of damage to the bag from the grasper/tenaculum. However, a lower risk grasper does not alter the risk of damage to the bag from the morcellator tip. Careful adherence to the training provided and the Instructions for Use regarding placement and visualization of the tip remains critical.
- To prevent risk of contamination, do not re-use the laparoscope following removal of the PneumoLiner.
- Appropriate pre-operative diagnostic testing should be completed prior to using this device.
- This device should only be used by surgeons with advanced training in laparoscopic techniques.
- This device should only be used by surgeons who have successfully completed the validated training program.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS AND PRECAUTIONS.

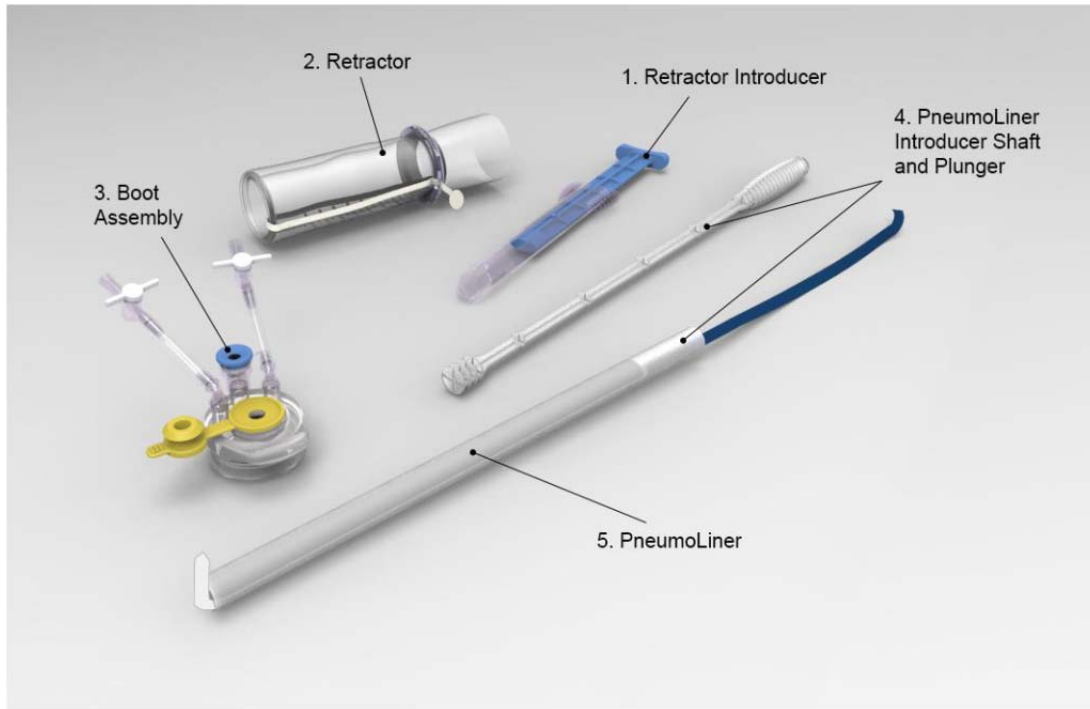
DEVICE DESCRIPTION

The PneumoLiner System consists of two main components:

- A laparoscopic multi-instrument port
- Tissue pouch (PneumoLiner) intended to provide a separately contained space within the abdomen for the safe morcellation of tissue

As depicted in Figure 1 below, the laparoscopic multi-instrument port consists of the Retractor, Retractor Introducer and the Boot Assembly.

Figure 1: PneumoLiner System Components

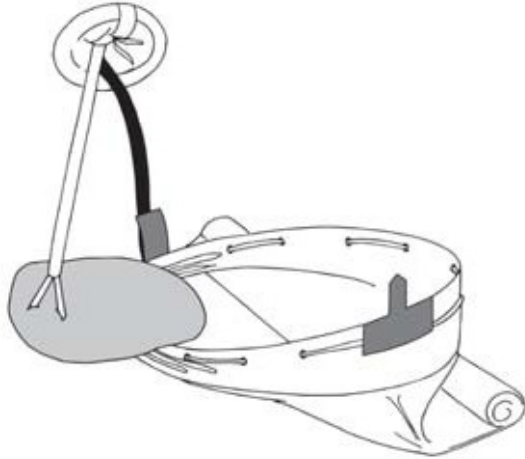


The Retractor Introducer is placed through the abdominal incision (20-25 cm) to deliver the distal ring on the Retractor. The Retractor retracts the incision to allow passage of laparoscopic instruments. The Retractor provides a gas-tight seal between the device and the incision. It also provides an anchor for the Boot Assembly.

The Boot Assembly consists of two insufflation ports and two instrument ports. The insufflation ports are used for the delivery of gas for distension and the venting of smoke during the course of the procedure. The ports consist of a large instrument valve port which is intended for the introduction of the PneumoLiner pouch/Morcellator and a 5 mm valve port which can accommodate a 5 mm instrument such as a laparoscope or grasper. (The large instrument valve also includes a reducer such that the opening can be reduced to 5 mm for smaller instruments.)

The PneumoLiner pouch is preloaded into the Introducer. The PneumoLiner Introducer Shaft is inserted through the Large Instrument Valve in the Boot Assembly. The PneumoLiner Introducer Plunger is then pushed into the Shaft to eject the PneumoLiner pouch into the abdominal cavity. As shown in Figure 2, an opening ring on the neck of the PneumoLiner pouch ensures that it is kept open. After the specimen is placed in the PneumoLiner pouch, a tether provides the mechanism for closing the PneumoLiner pouch and exteriorizing the collar section.

Figure 2 – Tissue specimen being placed in PneumoLiner pouch



The Boot Assembly is reattached inside the exteriorized PneumoLiner pouch enabling inflation of the PneumoLiner pouch and re-establishing pneumoperitoneum. The printed grid pattern allows for distinction between the tissue sample and the retracted viscera. The morcellation can then be conducted under direct visualization.

After morcellation is complete, the PneumoLiner pouch is deflated and the boot assembly is removed. The PneumoLiner pouch is then removed followed by the retractor.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The PneumoLiner System includes materials and colorants that have direct and indirect patient contact for a duration of up to 6 hours. The complete device in its final, finished form was subject to biocompatibility testing in accordance with ISO 10993-1: Biological evaluation of medical devices, Part 1: Evaluation and Testing. The PneumoLiner System is an externally communicating device, contacting tissue/bone/dentin for limited duration <24 hours. Therefore, the following tests were conducted:

- Cytotoxicity (b) (4))
- Sensitization (b) (4))
- Irritation/Intracutaneous Reactivity (b) (4))

The results demonstrated the PneumoLiner System is non-cytotoxic, non-sensitizing, and non-irritating.

SHELF LIFE/STERILITY

The PneumoLiner (port and pouch) is provided sterile for single use. The device is sterilized (b) (4) to achieve a sterility assurance level of 10^{-6} . It is packaged in a blister tray with a Tyvek lid. The sterilization validation was conducted in accordance with ISO 11137:2006.

Samples of the device were subjected to accelerated aging to simulate a 1 year shelf life. Device samples were evaluated for visual inspection and barrier properties (seal strength and bubble leak) in accordance with the following standards:

- Visual inspection per ASTM F1886: 2009 (2013)
- Bubble Leak testing per ASTM F2096:2011
- Seal Strength per ASTM F88:2009

Fifteen samples were used for the visual inspection and bubble leak tests. Sixty samples were used to assess seal strength. All samples passed.

Device functionality was assessed following 1 year of accelerated aging. Thirty-five samples representing the final, finished product were assessed using a protocol that mimics the design verification testing described in the bench testing section of this summary. In summary, the samples were put through the steps of a simulated use and assessed for leakage. At the completion of the simulated use, the PneumoLiner pouch was filled with (b) (4) water and inspected for leaks. This was followed by bond and material strength testing of the device components. The tested samples met the test acceptance criteria.

The information provided supports a 1 year labeled shelf-life for the PneumoLiner System.

PERFORMANCE TESTING – BENCH

Barrier Testing

The purpose of the Barrier Testing was two-fold:

- To demonstrate that the pouch material is impermeable to human cells through use of bacteria smaller than a human cell (filter test), i.e., *Brevundimonas diminuta*; and
- To demonstrate the integrity of the PneumoLiner pouch post-morcellation (immersion test).

Before performing the barrier testing, the sponsor validated the initial cleaning and sterilization step to ensure that bacterial cultures are not present at the beginning of the tests. In addition, the sponsor determined the minimum concentration of *B. diminuta* that could be identified visually (b) (4).

Filter Testing

The first barrier test was a filter test. The method involved filtration of Tryptone Soya Broth (TSB) containing *B. diminuta* through sections (discs) of PneumoLiner pouch which included a seam.

In summary, the PneumoLiner pouch material was placed between two containers. (b) (4)
(b) (4)
(b) (4). Twenty five samples were tested.

The Sterile TSB collection container was incubated (b) (4) along with positive controls (PneumoLiner pouch with pinhole and “spiked TSB”) and a negative control (TSB). There was no evidence of growth in the 25 samples and the positive and negative controls performed as expected.

The results of the testing are acceptable and validate the utility of this method.

The filter barrier testing was repeated on samples of PneumoLiner pouch that had undergone 1 year of accelerated aging. Each sample (b) (4) e of the PneumoLiner pouch such that it included the seam. Thirty-three samples (32 test and 1 control) were tested. The 32 test samples all passed with no evidence of growth of bacteria when challenged with (b) (4) (b) (4) *B. diminuta*. The positive control sample, PneumoLiner pouch with pin hole, had evidence of growth.

The pass criteria for the filter barrier test required superiority against an 85% rate of passing the leakage test. Based on zero failures in this sample of 32, the estimated lower

bound for passing the leakage test is 0.893, based on a 95% confidence interval.

The information provided on the filtration testing is sufficient to support the impermeability of the PneumoLiner pouch material including the seam to cells greater than the size of bacteria.

Immersion Testing

The second barrier test was an immersion test to assess PneumoLiner pouch permeability. The PneumoLiner pouch was filled with sterile TSB, (b) (4)

The PneumoLiner pouch was removed, then incubated (b) (4), and checked for growth of bacteria. Positive controls (PneumoLiner pouch with a pinhole leak and PneumoLiner pouch with TSB inoculated with *B. diminuta*) and a negative control were tested as well.

There were issues with the (b) (4) used; however, twenty-five samples were tested with no evidence of *B. diminuta* following incubation.

The results of the testing are acceptable and validate the utility of this test method.

The testing was repeated with devices that had been subjected to powered morcellation. As a result of the issues with the (b) (4) noted during the validation testing, the sponsor revised the protocol to incorporate a check of the (b) (4) during the immersion test, including the following checkpoints:

- Post morcellation
- Post application of the (b) (4)
- Post initial incubation
- Post immersion

If a leak was noted at the (b) (4), the rest of the device was checked for a leak. If the only leak noted was at the (b) (4), the sample was excluded from the test results. If a leak was also discovered elsewhere in the device, the sample was included in the analysis. In addition, the sponsor also excluded any samples which showed the presence of bacteria other than the test bacteria explicitly included as part of the test environment.

In the first test group, the sponsor included 35 samples, 32 test and 3 controls. Six samples in the test group were excluded because they failed the initial leak test following (b) (4). Following immersion, no samples were excluded. Four samples in the test group were excluded due to the growth of aberrant bacteria. The remaining 22 samples in the test group were included in the analysis. All of these samples passed and the 3 samples in the control group performed as expected.

As a result of having to exclude a number of samples from further analysis due to the presence of other bacteria, the protocol was revised to require (b) (4) prior to the immersion test to rule out those samples in which aberrant bacteria were noted.

Since the number of samples available for analysis was smaller than the sample size calculated to test the hypothesis, additional samples were procured. An additional 24 samples were evaluated under the revised protocol, 3 samples were excluded for leaks following (b) (4). An additional six were excluded for contamination following the incubation period. Of the 15 samples remaining, 12 were designated as test samples and 3 as controls. These samples were immersed. Two of the test samples were excluded for leak following the incubation. There were a total of 10 test samples in the analysis and 3 controls. The 10 test samples all passed and the controls performed as expected.

The immersion testing was designed to detect superiority against a set failure rate using a one sided significance level of 0.025 and 90% power. The maximum allowable failure rate was set at 0.125 (12.5%). Using these values, the calculated required sample size is 28 samples. Given that a total of 32 samples were tested without any failures, the upper bound on the 95% confidence interval was a failure rate of 0.107.

In summary, of the 59 total devices selected for immersion testing, only 38 samples were considered in the analysis (32 test samples and 6 controls.) While the number of test samples that had to be excluded from analysis was unexpected, the exclusions were defined *a priori* and were acceptable given the challenges posed by the test method and the test environment.

Overall, the barrier testing conducted supports that the PneumoLiner pouch materials are impermeable to bacteria, which are smaller than human cells, and the device following powered morcellation maintains its integrity when used in accordance with the parameters identified within the labeling.

Preliminary Bench Testing

The sponsor provided a set of initial tests intended to generate acceptance criteria for their design verification tests as well as to validate the surgical simulator and training rig developed specifically for the PneumoLiner System. The sponsor also performed some preliminary tests to profile the strength characteristics of the device. These tests, summarized below, did not include acceptance criteria:

- Laparoscope – evaluated the force required for the laparoscope to puncture the PneumoLiner pouch material. The minimum force to puncture (b) (4) 30 test samples.
- Tenaculum – evaluated forces required for grabbing the material and damaging the material using tenacula at different angles and forces. Each of 5 different tenacula was tested with 30 material samples. Two of the five tenacula were able

to damage the material when open. The minimum force required (b) (4) Most of the tested tenacula caused damage to bags when scraped along them. (As a result of this finding, a safety statement was added to the labeling.)

- **Powered Morcellation** – Each of the available powered morcellators (5 different brands) was used once in a simulated use test rig with the PneumoLiner pouch insufflated to intentionally attempt to contact the liner with the tip. The volume in the rig was decreased using inserts. In all cases the morcellator could contact the PneumoLiner pouch, if it were pushed at an extreme angle to the side, which was not reflective of the expected use or even probable misuse, as the morcellator is used at an angle of 70° to 90° to the abdominal wall. (As a result of this finding, additional safety statements were added to the labeling.)
- **Pressure/Burst Testing** – Thirty PneumoLiner System samples were evaluated. The PneumoLiner pouch was insufflated (b) (4) intended pressure, (b) (4) (b) (4) a simulated use test rig (b) (4). No damage was noted. The PneumoLiner pouch samples were then attached to compressor and inflated to burst. The minimum pressure recorded at failure (b) (4).
- **Obstruction Testing** – A large tissue specimen (one that cannot fit through the incision) was placed inside the PneumoLiner pouch. A force gauge was attached to the collar of the PneumoLiner pouch and the force required to remove the device from the incision was recorded. In the 30 samples tested, no failures were noted at (b) (4) force of the gauge.

Design Verification

Design verification testing was conducted using various laparoscopic instruments including graspers, laparoscope, variety of tenacula (including representative samples of the different types of grasping jaws), and various morcellators. There were nine separate tests intended to assess device performance. Each of these tests included 30 or more device samples. Table 1 below includes the steps within each test that included quantitative acceptance criteria.

Table 1 – Design Verification

Test	Acceptance Criteria	Results
Test 1 Inspection of Components		
	Components match color and description, free from damage and no sharp edges, features	Pass
Test 2 Performance and Set-up of Retractor		
<ul style="list-style-type: none"> • Retract a section (b) (4) mm thick abdomen and maintain incision opening 	Incisions remain retracted after 3 hours	Pass
<ul style="list-style-type: none"> • Removal Force 	(b) (4)	Pass
<ul style="list-style-type: none"> • Time to set-up retractor 		Pass
Test 3 Set-up and Use of Boot Assembly		

	(b) (4)	
• Time to attach boot		Pass
• Time to remove boot		Pass
• Flow Rate		Pass
• Time to attach Reducer from Large Instrument Valve		Pass
• Time to remove Reduce from Large Instrument Valve		Pass
• Leakage rate		Pass*
Test 4 Set-up and Use of PneumoLiner System		
• Time to insert PneumoLiner System	<(b) (4)	Pass
• Time to remove PneumoLiner System	<(b) (4)	Pass
Test 5 Inspection of components, assemblies, seams		
	No leakage when PneumoLiner filled with (b) (4)	Pass
Test 6 Base Retractor Assembly		
• Inner Proximal Ring to Retracting Sleeve Weld	(b) (4)	Pass
• Removal Ribbon to Inner Proximal Ring Weld	(b) (4)	Pass
• Retracting Sleeve Seam Weld, 25 mm section	>(b) (4)	Pass
Test 7 Boot Assembly		
• Insufflation tubing to boot assembly	(b) (4)	Pass
• 5 mm valve to Boot bond		Pass
• Reducer valve to Large valve assembly	(b) (4)	Pass
• Large Valve to Boot Bond	(b) (4)	Pass
Test 8 PneumoLiner Pouch Assembly		
• Proximal tab to PneumoLiner pouch	(b) (4)	Pass
• Distal Tab to PneumoLiner pouch		Pass
• PneumoLiner pouch tether to Opening Ring		Pass
• Opening ring crimp		Pass
• PneumoLiner pouch body weld at bottom end, 25 mm section		Pass
• PneumoLiner pouch body weld at corner, 25 mm		Pass

section	(b) (4)	
<ul style="list-style-type: none"> PneumoLiner pouch body weld at side, 25 mm section 		Pass
<ul style="list-style-type: none"> PneumoLiner pouch weld between body and collar, 25 mm section 		Pass
Test 9 Forces required to use PneumoLiner System		
<ul style="list-style-type: none"> Insert Distal Ring 	(b) (4)	Pass
<ul style="list-style-type: none"> Retract Sleeve 		Pass
<ul style="list-style-type: none"> Attach Boot 		Pass
<ul style="list-style-type: none"> Insert Introducer 		Pass
<ul style="list-style-type: none"> Eject PneumoLiner pouch 		Pass
<ul style="list-style-type: none"> Attach Reducer 		Pass
<ul style="list-style-type: none"> Remove Reducer 		Pass
<ul style="list-style-type: none"> Remove Opening Ring 		Pass
<ul style="list-style-type: none"> Remove Boot 		Pass
<ul style="list-style-type: none"> Exteriorize pouch 		Pass
<ul style="list-style-type: none"> Open PneumoLiner pouch 		Pass
<ul style="list-style-type: none"> Remove PneumoLiner pouch 		Pass
<ul style="list-style-type: none"> Remove Retractor 		Pass

**Due to one observation in which passage of a large instrument through the valve resulted in a leakage rate of (b) (4) diameter of the valve was decreased (b) (4). Testing repeated on the revised design met the acceptance criteria.*

Clinical Simulation of Morcellation

Simulated use testing was conducted to determine the ability of the PneumoLiner pouch to withstand morcellation using animal tissue, and to validate the test method for finding leaks/punctures following use. A total of 34 PneumoLiner pouches and 5 PneumoLiner System boot assembly and retractors were used for the testing along with the following laparoscopic instruments: graspers, trocars, laparoscope, variety of tenacula, and variety of morcellators (including electromechanical and bipolar). (All PneumoLiner pouches were initially checked for leaks as described in Test 2 below.)

In Test 1, simulated use was carried out in a surgical simulation test rig (SSTR). Of the 34 PneumoLiner Systems used, the first ten tests were run using lamb heart as the tissue specimen, and the final twenty-four with beef tongue to assess different tissue characteristics. Morcellation was carried out in the insufflated PneumoLiner pouch using one of three different morcellators. Tissue specimen weights ranged from (b) (4). The time to morcellate ranged (b) (4). Operator experience and tissue type played a role in the time. The weight of tissue morcellated ranged from (b) (4) the weight remaining in the PneumoLiner pouch was (b) (4).

The tissue remaining in the PneumoLiner pouch (b) (4)

The largest force measured was (b) (4). This was below the 200N minimum force the bag can withstand.

Test 2 was a leak test. Each of the 34 samples above was cleaned and dried. (b) (4)

r. Each inspection was carried out (b) (4). No bags were noted to have a leak. These samples were then used in the barrier testing previously described.

PERFORMANCE TESTING – ANIMAL &/OR CADAVER

Testing in an animal model was used for training validation and design validation.

PneumoLiner System Training Validation

The training program developed by the device manufacturer was validated through testing in a porcine model, using participants with a range of experience in laparoscopic procedures. The training validation consisted of the following steps:

1. A study coordinator shows and describes use of the PneumoLiner System while participant reads the Instructions for Use (IFU).
2. Assisted device set up and use in which the coordinator assists the participant in set up and use of the PneumoLiner System in the training rig.
3. Participant sets up and uses the PneumoLiner System without assistance in the training rig.
4. Participant sets up and uses the PneumoLiner System in a porcine model (beef tongue in various sizes used for morcellation specimen).

Thirty-four participants with a range of experience in laparoscopy were recruited. Each participant used at least 3 PneumoLiner Systems in the training. Four different morcellators were used (2 bipolar and 2 electromechanical). The following table, Table 2, provides a breakdown of device usage by operator experience:

Table 2 – Training Validation: Operator Experience

	Experienced	Inexperienced
Mechanical Morcellators	8	5
Bipolar Morcellators	13	8
Total	21	13

All users were able to successfully set up and use the PneumoLiner System.

Following inspection with a water leak test, no PneumoLiner Systems were observed to have a leak. The users reported that the IFU was clear and understandable; however, there were a few comments provided by the users that were incorporated into the training and a revised IFU for further clarity and emphasis.

With no failures noted in the 34 tests, the estimated lower bound on the 95% confidence interval for leakage is 0.898. This was greater than the 0.875 limit set for passing this test. (Note: A total of 102 PneumoLiner Systems were used in total during this test with no evidence of leak.)

This testing demonstrates that both inexperienced and experienced users can be trained to perform a contained morcellation without compromising the PneumoLiner System and can successfully use the device.

Design Validation for PneumoLiner System

The purpose of the study was to show that the PneumoLiner System can be used safely and effectively. Specifically, the primary outcome was to assess whether surgeons in a clinical setting can damage the PneumoLiner pouch. The secondary outcomes are based on successful set up and use of the device, and that it meets user needs, e.g., it was effective in containing the tissue.

Participants from the training validation study participated in this study, with the exception of 3 subjects from the inexperienced cohort. Each participant (n=31) used one PneumoLiner System in a porcine model with beef tongue for the morcellation specimen. Specimen sizes tested ranged from approximately (b) (4), with three samples (b) (4) range. Table 3 provides a breakdown of morcellator type by experience level:

Table 3 – Design Validation: Operator Experience

	Experienced	Inexperienced
Mechanical Morcellators	8	5
Bipolar Morcellators	13	5
Total	21	10

Each participant performed set up and use of the morcellator. Following removal, the test coordinator performed a leak test on the PneumoLiner pouch. The PneumoLiner pouch was filled with water (b) (4) and observed for leaks.

In all cases the users were successful in carrying out the procedure. There were no observed leaks following the procedure. There were a few comments from participants that were incorporated into the training and instructions for use for additional clarity.

With no device failures noted in 31 tests, the lower bound on the 95% confidence

interval for success was 0.889. This exceeded the minimum value of 0.875 set in the sample size calculation. (As described above for the immersion test, a simple superiority test was set with a value of 0.875 with a 90% power and 0.025 alpha. The difference is that this was described as a test of success whereas the immersion test was described as a test of failure; therefore 0.875 was used here as opposed to the 0.125 used in the immersion test. The same method for determining the target success/failure was used.)

The nonclinical testing conducted on the bench and in an animal model demonstrates that the PneumoLiner System meets its design and performance specifications and can be successfully used by physicians without evidence of leakage.

SUMMARY OF CLINICAL INFORMATION

The nonclinical testing serves as a surrogate for clinical testing for establishing reasonable assurance that the PneumoLiner System will maintain its integrity and will not allow transit of cellular debris following laparoscopic power morcellation procedures. The bench and animal testing provide a rigorous assessment of the design and performance of the device and are adequate to support the use of the device in women who may currently undergo uncontained laparoscopic power morcellation. Because this testing was conducted on the bench and in animal models instead of in humans, the testing conditions could be made more challenging to evaluate the device under worst case conditions. The submission also included testing that demonstrated that gynecologists with varying levels of experience could successfully use the device under simulated use conditions following completion of the training program developed by the sponsor. These tests were adequate to support the use of the device in women who may currently undergo uncontained laparoscopic power morcellation.

LABELING

The labeling meets the requirements of 21 CFR §801.109 for prescription devices.

The PneumoLiner System Instructions for Use address the known hazards and risks of the procedure and incorporate safety statements to mitigate these risks. The labeling includes:

- Information on the types of morcellators, laparoscopes, graspers with which the device has been demonstrated to be compatible.
- The intended use population.
- Safety instructions intended to minimize the risk of contact of surgical instruments with the inside of the PneumoLiner pouch.
- Safety instructions emphasizing the importance of visualization of the tenaculum/grasper and morcellator tip at all times.
- Risk information in a boxed warning that physicians should share with patients regarding the potential for uterine tissue to contain an undetected cancer, potential for a

laparoscopic power morcellator to spread cancer, and the lack of clinical demonstration of a reduction in risk when using a containment system.

- The use of the device requires training of the user. Clinicians using the PneumoLiner System must be physicians who have familiarized themselves with the PneumoLiner System Instructions for Use and have undergone training in the use of the device.

The contraindications identified in the PneumoLiner labeling contribute to the defined indications for use for the PneumoLiner. Removal or modification of any of the contraindications, for new and already cleared devices [see 21 CFR 807.81(a)(3)], will require submission of a premarket notification [510(k)], which includes clinical performance testing to demonstrate that users can use the device to contain the tissue specimen for the intended patient population.

The information in the boxed warning is considered necessary for identifying the benefits and risk of the PneumoLiner procedure.

RISKS TO HEALTH

Table 4 below identifies the risks to health that may be associated with use of the Gynecologic Laparoscopic Power Morcellation Containment System and the measures necessary to mitigate these risks.

Table 4: Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Adverse tissue reaction	Biocompatibility
Infection	Sterilization Validation Shelf Life Validation Labeling
Intraperitoneal tissue dissemination (benign or malignant) <ul style="list-style-type: none"> • Material permeability • Improper function of containment device • Inadequate material strength • Physical trauma to liner caused by contact with morcellator or grasper/tenaculum • Damage to liner (intentional or accidental) from instrument inserted through secondary port • Tearing during removal with loss of contents into abdominal cavity • Use error 	Non-clinical Performance Testing (Bench and Animal) Shelf Life Validation Labeling Training

<p>Traumatic injury to non-target tissue/organ</p> <ul style="list-style-type: none"> • Active end of morcellator or grasper/tenaculum breaches liner • Loss of insufflation • Inadequate space to perform morcellation • Inadequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera • Use error 	<p>Non-clinical Performance Testing (Bench and Animal) Labeling Training</p>
<p>Hernia through abdominal wall incision</p>	<p>Labeling Training</p>
<p>Prolongation of procedure and exposure to Anesthesia</p>	<p>Labeling Training</p>

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the Gynecologic Laparoscopic Power Morcellation Containment System is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Device components that are labeled sterile must be validated to a sterility assurance level of 10^{-6} .
3. Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the intended shelf life.
4. Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be 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 must be developed and validated to ensure users can follow the instructions for use.
6. Labeling must include:

- Contraindication for use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- Unless clinical performance data demonstrates that it can be removed or modified, a 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.
- 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.

BENEFIT/RISK DETERMINATION

The risks of the PneumoLiner System are based on nonclinical laboratory studies (bench and animal). The risks associated with the use of the device include intraperitoneal tissue dissemination, traumatic injury to non-target tissue/organ, infection, hernia through abdominal wall incision, adverse tissue reaction and prolongation of procedure.

The probable benefits of the PneumoLiner System are also based on nonclinical laboratory studies (bench and animal). The benefits of the device include containment of tissue during laparoscopic power morcellation and the associated ability to perform a minimally invasive surgery. The nonclinical testing serves as a surrogate for clinical testing for establishing reasonable assurance that the PneumoLiner System will maintain its integrity and will not allow transit of cellular debris following laparoscopic power morcellation procedures.

The PneumoLiner System also offers the benefit of inflation of the containment system and visualization within the containment system. These two benefits allow for the creation of a working space around the specimen and visualization of the morcellator tip during morcellation. The single port design provides the additional benefits of single site surgery.

In conclusion, given the available information, the data support that when the PneumoLiner System is used in accordance with the intended population identified in the labeling for laparoscopic power morcellators, the probable benefits outweigh the probable risks. The device provides substantial benefits and the risks can be mitigated by the use of general and the identified special controls.

CONCLUSION

The *de novo* for the PneumoLiner is granted and the device is classified under the following:

Product Code: PMU

Device Type: Gynecologic Laparoscopic Power Morcellation Containment System

Class: II

Regulation: 21 CFR 884.4050