February 25, 2020

Advanced Surgical Concepts
% Jonathan Kahan
Partner
Hogan Lovells US LLP
Columbia Square, 555 Thirteenth Street, NW
Washington, DC 20004

Re: K192898
Trade/Device Name: PneumoLiner
Regulation Number: 21 CFR 884.4050
Regulation Name: Gynecologic Laparoscopic Power Morcellation Containment System
Regulatory Class: II
Product Code: PMU
Dated: October 11, 2019
Received: October 11, 2019

Dear Jonathan Kahan:

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 Sharon M. Andrews
Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K192898

Device Name
PneumoLiner

Indications for Use *(Describe)*
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.

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

Advanced Surgical Concepts' PneumoLiner

Submitter

Advanced Surgical Concepts Ltd.
Unit 4 Sunnybank Center
Upper Dargle Road
Bray County
Wicklow A98 E339
Ireland

Phone: +353 1 286 4777
Facsimile: +353 1 286 4776

Contact Person: Edward Hyland
Date Prepared: February 7, 2020

Name of Device: PneumoLiner

Common or Usual Name: Gynecologic Laparoscopic Power Morcellation Containment System

Classification Number: 21 C.F.R. §884.4050

Classification Name: Gynecologic Laparoscopic Power Morcellation Containment System

Regulatory Class: Class II

Product Code: PMU

Predicate Device

Advanced Surgical Concepts Ltd. PneumoLiner DEN150028

Classification Name: Gynecologic Laparoscopic Power Morcellation Containment System
Regulatory Class: Class II
Product Code: PMU

This device has never been the subject of a recall, design related or otherwise.

Device Description

The ASC PneumoLiner is an inflated morcellation containment system that allows for containment of gynecological tissue, cells and fluids during power morcellation and removal. It is a sterile single use device and requires the surgeon to successfully complete a validated training program before use. The ASC PneumoLiner is for clinical use in a hospital or surgical center operating room.

The device consists of the following components: the Retractor, Retractor Introducer, Boot Assembly, the PneumoLiner Introducer and the PneumoLiner. The first three components (Retractor, Retractor Introducer and Boot Assembly) are used to retract an incision in the abdominal wall and to allow for the introduction of laparoscopic instruments and the PneumoLiner Bag while under pneumoperitoneum and with vision from a laparoscope. The PneumoLiner Bag is introduced via the PneumoLiner introducer and the large valve on the Boot Assembly.

The PneumoLiner is intended for use in gynecological power morcellation. It is intended to form a complete containment barrier from the spillage of liquids, cells and tissue from the time the tissue or organ is excised and encapsulated in the PneumoLiner bag, throughout the morcellation procedure and withdrawal of the containment bag with accompanying liquids and debris.

The key technological characteristics of the PneumoLiner and predicate PneumoLiner are the following:

- The PneumoLiner is designed to be deployed while the abdomen is under pneumoperitoneum. This ensures an easy deployment and correct placement of the PneumoLiner within the peritoneal cavity.
- The PneumoLiner is designed to open once deployed in the abdomen so as to facilitate placement of the tissue sample in the device.
- The device is designed to close and encapsulate the tissue sample prior to exteriorisation of the neck.
- Once the PneumoLiner is inflated and pneumoperitoneum is re-established, the inserted morcellator is not intended to come into contact with the sides of the PneumoLiner during a morcellation.
- The inflation of the PneumoLiner retracts the viscera and expands the abdominal wall to create a space for morcellation.
- Morcellation takes place in the contained space of the PneumoLiner under vision with the aid of a laparoscope.
- The size of the PneumoLiner is designed to create a large working space within the abdomen.
- The grid pattern allows for a surgeon to easily distinguish between the target tissue/organ inside the PneumoLiner and viscera on the outside of the PneumoLiner.

The PneumoLiner Bag is polyurethane with nylon tether/tabs and a nitinol opening ring with stainless steel crimp. The Retractor Introducer shaft is polycarbonate. The Retractor Introducer Plunger is HDPE with a blue colorant. The Retractor sleeve is polyurethane with polycarbonate, nylon and lubricant oil. The Boot Assembly component includes PVC, adhesive, polyurethane, HDPE and polycarbonate. The instrument valves are polycarbonate housings with silicone valves with blue and yellow colorants. The PneumoLiner introducer shaft and plunger are both HDPE. The PneumoLiner System includes materials and colorants that have direct and indirect patient contact for a duration of up to 6 hours.

Intended Use / Indications for Use

The purpose of the 510(k) notice is to revise the Indications for Use and contraindications of the predicate PneumoLiner device cleared to market under DEN150028 to better define the patient population.

The indications for use for the cleared PneumoLiner (DEN150028) are:

> 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 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.

This 510(k) modifies the indications for use to add the following sentence: “When used in women with fibroids, the PneumoLiner is for women who are pre-menopausal and under age 50.”

Thus, the indications for use for the subject device are:

> 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.

Further, the 510(k) also modifies the contraindications for the PneumoLiner. The cleared PneumoLiner (DEN150028) contains the following contraindication:

> 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.

This contraindication has been changed to read:

> 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 purpose of these changes is to better inform the physician of the intended patient population. This change to the wording of the contraindication does not alter the patient population but better defines it, removing the ambiguity of the term “peri-menopausal.” The basis for these changes is the published clinical literature that is referenced in the Summary of Clinical Performance Testing below.

The proposed minor revisions to the indications for use and contraindication are to better identify the population of women indicated for use of the PneumoLiner; therefore, these changes do not represent a new intended use.

The labeling was also modified to include a new warning to reflect the increased risk of occult cancer with age. The warning states:

> The risk of occult cancer, including uterine sarcoma, increases with age, particularly in women over 50 years of age. This information should be shared with patients when considering surgery with the use of these devices.

Summary of Technological Characteristics

Containment through inflation and an impervious bag material is the technological principle for both the subject and predicate device. This is supported by retraction of viscera through the inflation of the bag and vision provided through the 5mm instrument valve by a laparoscopic endoscope to enable power morcellation of the subject gynecological tissue.

Both the subject PneumoLiner and the predicate PneumoLiner use identical technological elements. All components of the devices are the same.

	Subject PneumoLiner	PneumoLiner DEN150028
Device Components	The Retractor Retractor Introducer The PneumoLiner Introducer PneumoLiner (bag)	Same
Accessories	N/A	N/A
Power Source	N/A	N/A
Materials	Polyurethane, nylon, PVC, silicone, polycarbonate, adhesive, stainless steel, blue and yellow colorants	Same
Sterilization	Gamma irradiation	Same
Shelf Life	3 years	1 year
Packaging	Hard blister with retainer insert and Tyvek	Hard blister and Tyvek

The changes to shelf-life and packaging do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

- Sterilization validation to ISO 11137-1:2006 and ISO 11137-2:2013
- Shelf life testing on samples accelerated aged which underwent simulated shipping including:
  - Sterile Barrier Integrity testing

- Visual inspection per ASTM F1996:2009 (2013)
- Bubble leak testing per ASTM F2096:2011
- Seal strength per ASTM F88:2009.

- Device functionality
  - Leak testing
  - Bond/material strength testing.

Summary of Clinical Performance Testing

The purpose of 510(k) K192898 is a revision to the labeling; contraindication and the indication for use statement to better define the patient population. The rationale for the proposed label changes is published clinical literature as reflected in the JMIG Special Article, "Morcellation during Uterine Tissue Extraction: An Update by the Tissue Extraction Task Force Members" published in *Journal of Minimally Invasive Gynecology, Vol 25, No 4, May/June 2018* and the recent FDA paper; *FDA Updated Assessment of the Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids (December 2017* [1] that stratify the risk of occult leiomyosarcoma (LMS) by age which provides a better- defined method to allow surgeons to mitigate the risk to their patients.

There are no clinical data, of which the company is aware, which supports an increased risk of LMS due to menopausal status. The most complete meta-analysis is included in the paper by Seidhoff et al[2] which indicates a relationship between age and risk of LMS but does not find any evidence of a relationship to menopausal status in the literature.

The FDA Updated Assessment of the Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids (December 2017) has summarized the risk of uterine sarcoma and LMS by age. The stratification by age has clearly defined 50 years as a significant and easily defined marker; that is, there is a notably reduced risk for women under 50 years of age for the occurrence of both uterine sarcoma and LMS.

The available data has also been reviewed as part of the AAGL Tissue Extraction Task Force paper "Morcellation During Uterine Tissue Extraction: An Update,"[3] which supports the conclusion that the older the patient with presumed fibroids, the greater the risk that the tumor is malignant.

Conclusions

The submitted published clinical data supports the labeling changes to the PneumoLiner and the nonclinical testing on packaging and shelf-life demonstrate that the device is as safe, as effective, and performs as well as the predicate.

[1] https://www.fda.gov/media/109018/download
[2] Seidhoff et al. 2017. Laparoscopic hysterectomy with morcellation vs abdominal hysterectomy for presumed fibroids: An updated decision analysis following the 2014 FDA safety communications. Am J Obstet Gynecol. 2017 Mar;216(3):259.e1-259.e6
[3] Morcellation During Uterine Tissue Extraction: An Update, Journal of Minimally Invasive Gynecology (2018), https://doi.org/10.1016/j.jmig.2018.03.010.