DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 7, 2016

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

Re: DEN150028
PneumoLiner
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 884.4050
Regulation Name: Gynecologic Laparoscopic Power Morcellation Containment System
Regulatory Classification: Class II
Product Code: PMU
Dated: June 19, 2015
Received: June 19, 2015

Dear Jonathan Kahan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the PneumoLiner, a prescription device under 21 CFR Part 801.109 that is indicated 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.* FDA concludes that this device should be classified into class II. This order, therefore, classifies the PneumoLiner, and substantially equivalent devices of this generic type, into class II under the generic name, Gynecologic Laparoscopic Power Morcellation Containment System.

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

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On June 19, 2015, FDA received your *de novo* requesting classification of the PneumoLiner into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the PneumoLiner into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the PneumoLiner indicated 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.*

can be classified in class II with the establishment of special controls for class II. FDA believes class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.
The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – 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) • 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
Traumatic injury to non-target tissue/organ (benign or malignant) • 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	Non-clinical Performance Testing (Bench and Animal) Labeling Training
Hernia through abdominal wall incision	Labeling Training
Prolongation of procedure and exposure to anesthesia	Labeling Training

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification

requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Gynecologic Laparoscopic Power Morcellation Containment System they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Veronica Price at (301) 796-6538.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health