December 19, 2017

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

Re: DEN170075
Trade/Device Name: ContainOR
Regulation Number: 21 CFR 878.4825
Regulation Name: General laparoscopic power morcellation containment system
Regulatory Class: Class II
Product Code: PZQ
Dated: September 29, 2017
Received: September 29, 2017

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 ContainOR, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The ContainOR is a bag containment system intended for use by qualified surgeons for tissue extraction and/or power morcellation during general laparoscopic procedures. The ContainOR 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ContainOR, and substantially equivalent devices of this generic type, into Class II under the generic name general laparoscopic power morcellation containment system.

FDA identifies this generic type of device as:

> **General laparoscopic power morcellation containment system**. A general 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 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 September 29, 2017, FDA received your De Novo requesting classification of the ContainOR. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ContainOR into class I or 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, for the previously stated indications for use, the ContainOR can be classified in class II with the establishment of special controls for class II. FDA believes that 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 the following table:

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life testing Labeling
Intraperitoneal tissue dissemination • 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 • Tearing of the bag due to stones contained in tissue • Use error	Non-clinical performance testing Animal performance testing Shelf life testing Labeling Training

Identified Risks to Health	Mitigation Measures
Traumatic injury to non-target tissue/organ • 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 Animal performance testing 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 general laparoscopic power morcellation containment system is subject to the following special controls:

Special Controls
(1) The patient-contacting components of the device must be demonstrated to be biocompatible. (2) Performance testing must demonstrate the sterility of patient-contacting components of the device. (3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life. (4) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested: (i) Demonstration of the device impermeability to tissue, cells and fluids. (ii) Demonstration that the device allows for the insertion/withdrawal of laparoscopic instruments while maintaining pneumoperitoneum. (iii) 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. (iv) Demonstration that compatible laparoscopic instruments and morcellators do not compromise the integrity of the containment system. (v) Demonstration that 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: • A contraindication for use in gynecological procedures. • A contraindication against use of tissue that is known or suspected to contain

Special Controls
malignancy. • The following boxed warning: "Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. The use of laparoscopic power morcellators may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk." • A statement limiting use of device to physicians who have completed the training program. • A 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 general laparoscopic power morcellation containment system they intend to market prior to marketing the device.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Cal Rabang at 301-796-6412.

Sincerely,

Angela C. Krueger -S

Angela Krueger
Deputy Dir., Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health