September 17, 2021

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

Re: K211234
Trade/Device Name: RedEx
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 20, 2021
Received: August 20, 2021

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,

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

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)*

K211234

Device Name

RedEx

Indications for Use *(Describe)*

The RedEx contained extraction system is indicated to contain and isolate tissue during, or prior to, surgical removal and /or extracorporeal manual morcellation.

Contraindications:

RedEx is contraindicated for use with laparoscopic power and manual morcellators.

RedEx 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)*

X 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 Ltd's RedEx

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: August 20, 2021

Name of Device:	RedEx
Common or Usual Name:	Tissue Bag
Classification:	21 CFR 876.1500, Accessory to Endoscope
Regulatory Class:	Class II
Product Code:	GCJ
Predicate Devices:	Applied Medical Resources Corporation's Applied Medical Tissue Containment System (K142427) a/k/a Alexis CES

Device Description

The Advanced Surgical Concepts Ltd, RedEx, is a contained extraction system; proposed under classification regulation 21 CFR 876.1500, device class II and product code GCJ.

The device is provided sterile for single use.

The RedEx consists of a flexible specimen containment Bag, with an integrated Opening Ring and Bag Tether and a separate Guard component to protect the Bag and incision.

The Bag is made from polyurethane (PU) film and comes preloaded in an Introducer. There is a Plunger to deploy the Bag into the abdominal cavity. Any FDA cleared 12mm trocar may be used as an accessory for device deployment. This is a standard sized trocar for use in laparoscopic surgery. A blue arrow on the Introducer provides the user with the correct orientation for insertion of the Introducer to ensure the Bag is correctly deployed.

After the Bag is ejected from the Introducer into the abdominal cavity, the mouth of the Bag returns to its original circular shape. The nitinol wire Opening Ring facilitates placement of the specimen in the Bag. When the specimen is encapsulated and ready for removal or extracorporeal manual morcellation the Bag Tether is pulled, closing the Bag. The Bag Tether and Opening Ring exit through the 12mm trocar, indicating the Bag is fully closed. The incision is then increased to the required size, 2.5-6cm, prior to removal of the trocar. The trocar is removed, and the mouth of the Bag is opened outside the abdomen. The free end of the Guard, which includes the Guard Petals and is opposite the end with the Guard Ring, is then inserted

through the mouth of the Bag followed by the Anchor Ring. The Guard is actuated by flipping the Rolling Ring inward until the incision is maximized. The Guard Petals, which are made from a tough polyethylene (PE) film, overlap and conform to the incision; protecting the incision and Bag material from inadvertent scalpel strikes and from the traumatic graspers that are used to grasp and hold the tissue specimen at the incision.

The physician then performs extracorporeal manual morcellation using manual surgical instruments (e.g., a grasper and a scalpel). When the tissue specimen has been removed, the surgeon flips the Rolling Ring in the opposite direction two or three times and pulls on the Removal Ribbon to remove the Guard. The Bag is removed by grasping the Opening Ring and carefully removing the Bag from the incision.

Intended Use / Indications for Use

The RedEx contained extraction system is indicated to contain and isolate tissue during, or prior to, surgical removal and /or extracorporeal manual morcellation.

Contraindications:

RedEx is contraindicated for use with laparoscopic power and manual morcellators.

RedEx 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.

Comparison of Technological Characteristics with the Predicate Device:

The subject and predicate devices are both tissue containment bags intended to retrieve and contain specimens during manual morcellation. Both devices are wholly inserted into the abdominal or pelvic cavity prior to specimen placement in the bag. If the specimen requires morcellation, both bags are brought up to the incision prior to manual morcellation.

The subject and predicate devices are based on the following identical technological elements:

- A specimen bag with an attached ring that opens once deployed in the abdominal cavity to aid encapsulation of the specimen for removal and/or extracorporeal manual morcellation at the incision site.
- A bag tether, attached to the bag and which remains external to the abdominal cavity, for exteriorization of the mouth of the bag to facilitate extracorporeal manual morcellation.
- A guard that maximizes the incision to allow for removal and/or extracorporeal manual morcellation at the incision site.

The following technological differences exist between the subject and predicate devices:

- The method of insertion of the bag into the abdominal cavity
- The guard technology; although the purpose of both guards is the same, the technology is different
- Use of different materials as described in the substantial equivalence information table.

Performance Data

Substantial Equivalence Testing

Side-by-side testing was carried out on both the subject and predicate devices to demonstrate substantial equivalence. The tests primarily focused on the durability of the containment bags and the performance of the guard components. Testing included:

- Bag material and seal strength
- Bag material puncture-resistance
- Guard puncture-resistance
- Guard coverage and security
- Simulated use

Functionality Testing

Additional testing was carried out on the subject device to evaluate its performance. Testing included:

- Microbial barrier testing
- Component durability testing
- Bench-top simulated use (with post-use leak testing)
- Simulated clinical use (with post-use leak testing)
- Human factors testing
- Packaging performance testing
- Stability testing

Biocompatibility

The subject device is a device that is in contact with tissue for a period of less than 24 hours. Evaluation of the biocompatibility of RedEx was carried out as per IS EN ISO 10993-1 Biological Evaluation of Medical Devices. The following biocompatibility testing was carried out by an independent laboratory (Toxikon):

- MTT Cytotoxicity test
- Intracutaneous Injection Test
- Kligman Maximization Test

All materials were found to be biocompatible.

Sterilization

ASC completed a sterilization validation using the standard VDmax 25 gamma radiation method as per *ANSI/AAMI/ISO 11137-2: Sterilization of Health Care Products – Radiation– Establishing the sterilization dose – Method VDmax*

In all instances, the RedEx functioned as intended and the results observed were as expected.

Substantial Equivalence Information				
	RedEx **K211234**	**Applied Medical Tissue Containment System** **K142427**	**Comparison**	**Testing**
Clinical Function	Specimen containment Bag Guard to protect Bag and incision	Specimen containment Bag Guard to protect bag and incision	Same	Simulated use testing
Sterility	Sterile, for Single use	Sterile, for Single Use	Same	Validated using VDmax25
Packaging	Device provided in a Tyvek/Polymer pouch	Device provided in a Tyvek/Polymer pouch	Same	Testing carried out following transit simulation: Bubble-leak testing Functionality testing Packaging seal testing
Physical Characteristics				
Bag Size	Volume: 6000mL Dimensions: 25cm x 36cm Opening Ring Diameter: 17.5cm	Volume: 3400mL Dimensions: 22cm x 30cm Opening Ring Diameter: 14cm Volume: 6500mL Dimensions: 27cm x 38cm Opening Ring Diameter: 17cm	Larger Opening Ring diameter Larger Bag capacity	Simulated use testing
Bag Composition	Polymer film material Nitinol ring at the mouth to open Bag Fabric tether attached to ring	Polymer film material Polymer ring at the mouth to open bag String tether attached to ring	Different Ring, Bag and retrieval tether materials	Bag seal strength testing (standalone & comparative) Bag puncture-resistance testing (comparative) Tether strength testing Biocompatibility testing Bacterial penetration testing
Guard	Guard with anchor ring, sleeve and adjustable petals Actuated/retracted by rolling down the Rolling Ring	Ratcheted guard strip Actuated by pulling open the guard	Different overall Guard design Both intended to maximize and protect	Simulated use testing (standalone & comparative) Post-use Bag leak-testing Guard puncture resistance (standalone &

Substantial Equivalence Information				
	RedEx **K211234**	**Applied Medical Tissue Containment System** **K142427**	**Comparison**	**Testing**
			the incision area	comparative) Guard security (comparative) Guard coverage (comparative)
Opening Ring	Composed of nitinol Welded inside a pocket at the mouth of the Bag that allows for closure Facilitates specimen encapsulation	Composed of thick polymer Welded directly to the bag and does not close Facilitates specimen encapsulation	Different materials Ring welded into a pocket to allow Bag closure.	Simulated use testing (standalone & comparative) Ring strength testing
Use				
Manual Morcellation Process	Opening ring exteriorized through incision Guard placed in mouth of Bag Manual morcellation undertaken	Opening ring exteriorized through incision Guard placed in mouth of bag Manual morcellation undertaken	Same	Simulated use
Bag Introduction Process	Bag provided pre-loaded in Introducer with Plunger. Delivered through a 12mm trocar accessory. Pneumoperitoneum maintained.	Bag folded before insertion Deployed through open incision. Pneumoperitoneum re-established after deployment.	Provided pre-rolled in an Introducer	Simulated use (standalone & comparative)
Incision size	2.5-6cm	2.5-4cm	Larger incision length range	Guard coverage testing (comparative) Guard security testing (comparative) Simulated use
Tissue Encapsulation	Tissue introduced into open mouth of Bag.	Tissue introduced into open mouth of bag. Bag cannot be closed	Bag is closed before exteriorization	Simulated use (standalone & comparative)

Substantial Equivalence Information				
	RedEx **K211234**	**Applied Medical Tissue Containment System** **K142427**	**Comparison**	**Testing**
	RedEx Bag can be fully closed by pulling on the tether			
Bag Removal	IFU instructs surgeon to pull upwards on Opening Ring	IFU instructs surgeon to pull upwards on Opening Ring and tether	No use of tether when removing	Simulated use testing (standalone & comparative)

Conclusions

RedEx is as safe and effective as the Applied Medical Tissue Containment System/Alexis CES. RedEx has the same intended use and indications, and similar technological characteristics and principles of operation as its predicate device. In addition, the minor technological differences between RedEx and its predicate device raise no new issues of safety or effectiveness. Thus, RedEx is substantially equivalent.