March 31, 2022

Applied Medical Resources Corporation
Apeksha Shanbhag
Regulatory Affairs Specialist
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K211043
Trade/Device Name: Alexis® Contained Extraction System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 3, 2022
Received: March 4, 2022

Dear Apeksha Shanbhag:

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,

Jason R. Roberts, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211043

Device Name
Alexis® Contained Extraction System

Indications for Use *(Describe)*
The Alexis® Contained Extraction System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation via an abdominal or vaginal approach.

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 – K211043

510(k) Submitter: Applied Medical Resources Corporation
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Preparation Date: March 30, 2022

Trade Name: Alexis® Contained Extraction System

Common Name: Tissue Bag

Classification: Regulation: 21 CFR 876.1500, Endoscope and Accessories
Device Class: Class II
Product Code: GCJ (endoscope and accessories)

Predicate Device: Applied Medical Tissue Containment System
510(k)#: K142427
Product Code: GCJ
The predicate device has not been subject to a design related recall.

Device Description: The Alexis® Contained Extraction System is a sterile, single use tissue bag with a guard system component. The polyurethane tissue bag consists of a flexible ring, tabs, strap with a snap fastener, and an attached tether. It is available in two models GTB14 and GTB17 with the following dimensions and volumes:

Model	Ring Diameter	Volume
GTB14	14 cm	3,400 mL
GTB17	17 cm	6,500 mL

The tissue bag is used to contain and isolate specimens for surgical removal and/or manual morcellation. The strap with snap fastener maintains the folded bag and flexible ring in a collapsed state during insertion. After the device is fully inserted and deployed into the abdominal or pelvic cavity, the opening of the bag returns to its original, circular shape, facilitating placement of the specimen in the bag. When

the specimen is ready for removal and/or manual morcellation, the tether, tabs, and strap are used to maneuver the ring to the surface of the extraction site.

If the specimen requires manual morcellation, the ring may be repeatedly flipped to shorten the bag and consequently bring the specimen closer to the extraction site.

The guard system consists of a guard and a self-retaining retractor. The guard is composed of a coiled polyethylene material that conforms to the extraction site. The self-retaining retractor consists of two polyurethane rings connected by a polyurethane sheath and a tether attached to the inner ring. It helps anchor the guard at the extraction site. The guard system provides a robust barrier between the bag and sharp instruments.

The Alexis® Contained Extraction System can be inserted and retrieved either through an abdominal incision or through the vaginal canal and colpotomy. In both cases, manual morcellation is performed extracorporeally at the extraction site.

Indications for use: The Alexis® Contained Extraction System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation via an abdominal or vaginal approach.

Comparison with the Predicate Device:

The subject and predicate devices are both single use tissue bags intended to retrieve and contain specimen during extracorporeal manual morcellation.

The following table provides a comparison with the predicate:

	Applied Medical Tissue Containment System (Predicate Device)	**Alexis Contained Extraction System (Subject Device)**
Intended use	To contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation	Same
Indications for use	Used to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation.	Used to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation via an abdominal or vaginal approach.
Description	Consists of a tissue bag and a guard component.	Consists of a tissue bag and a guard system component. The bag includes tabs and a strap with a snap fastener.
Size	Min: 10 cm diameter, 2,500 mL volume Max: 25 cm diameter, 20,000 mL	Min: 14 cm diameter, 3,400 mL volume Max: 17 cm diameter, 6,500 mL

	volume	volume
Anatomical Site	Bag is inserted and retrieved through an abdominal incision.	Bag is inserted and retrieved through an abdominal incision or colpotomy.
Packaging material	Mylar/Tyvek Pouch	Nylon/Tyvek Pouch
Sterilization method	Radiation sterilization	Ethylene Oxide (EO) sterilization

These differences in technological characteristics do not raise different questions of safety or effectiveness.

Discussion of Performance Data

The following performance data is provided in support of the substantial equivalence determination.

Biocompatibility

Biocompatibility evaluation of the subject device was conducted in accordance with ISO 10993-1, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and 2020 FDA guidance, "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The subject device contacts tissue for less than 24 hours, so the following endpoints were considered, and all materials were found to be biocompatible:

- Cytotoxicity
- Intracutaneous Irritation
- Sensitization
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

Sterilization/Shelf Life

Sterilization validation was performed in accordance with ISO 11135 – 2, *Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.*

Shelf life testing was performed to evaluate package integrity and device functionality following artificial aging and simulated transit conditioning.

Functional Performance

Design Verification testing was performed with the subject device. The following performance characteristics were evaluated:

- Integrity of tissue bag
- Integrity of tether to pull the tissue bag out of the extraction site
- Integrity of the guard system's material to protect the bag from incidental cuts

- Ability of the tissue bag to maintain a closed system
- Resistance of tissue bag material to penetration by blood-borne pathogens
- Ability of guard system to remain anchored at the extraction site
- Integrity of tabs and strap to assist in specimen capture
- Ability of snap fastener to withstand insertion and ability of the user to deploy for specimen capture

Additionally, simulated use testing was performed with the subject device in both an abdominal bench model and a vaginal bench model to ensure that the device would perform as intended. This testing demonstrated the subject device's capability to perform the intended use at the different anatomical sites of insertion and retrieval.

Conclusion:

Results of testing demonstrate that the subject Alexis® Contained Extraction System is substantially equivalent to the predicate Applied Medical Tissue Containment System, and that the subject device is as safe and effective as the predicate device.