November 1, 2023

Applied Medical Resources Corporation
Niharika Mirji
Associate Specialist
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K232880
Trade/Device Name: Inzii Ripstop Redeployable Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 15, 2023
Received: September 18, 2023

Dear Niharika Mirji:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.11.01 15:10:59 -04'00'

Mark Trumbore, 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

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)*

K232880

Device Name

Inzii® Ripstop Redeployable Retrieval System

Indications for Use *(Describe)*

Applied Medical's Inzii Ripstop Redeployable Retrieval System is indicated for use as a receptacle for the collection and extraction of tissue, organs, and calculi during general and laparoscopic surgical procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K232880

510(K) Submitter: Applied Medical Resources Corp.
22872 Avenida Empresa
Rancho Santa Margarita, CA, 92688
(949) 713-8000

Contact Person: Niharika Niranjan Mirji
Regulatory Affairs Associate Specialist
Applied Medical Resources Corp.
niharikaniranjan.mirji@appliedmedical.com
Tel: (949) 713-7579
Fax: (949) 713-8200

Date of Preparation: 05 October, 2023

Trade Name: Inzii® Ripstop Redeployable Retrieval System

Common Name: Specimen Retrieval System

Classification: Regulation: 21 CFR 876.1500, Endoscope & Accessories
Device Class: Class II
Product Code: GCJ

Predicate Device: Trade Name: Inzii Tissue Retrieval System
510(k) #: K060051
Device Class: Class II
Product Code: GCJ

Reference Device: Trade Name: Inzii Universal Retrieval System
510(k) #: K100959
Device Class: Class II
Product Code: GCJ

Device Description: The Inzii Ripstop Redeployable Retrieval System is a single-use device designed for the containment and extraction of multiple tissue specimens. The device consists of a flexible specimen bag and an introducer tube which can be redeployed for multiple uses within a single procedure. The product will be available in two models, a 10 mm model with a 265 ml specimen bag and a 15 mm model with a 1600 ml specimen bag size. The device is provided sterile and is constructed of a Ripstop nylon specimen bag, various polymers and stainless steel. The major differences between the predicate and the subject device include the subject device featuring a stronger Ripstop nylon specimen bag and the ability to be redeployed multiple times within a single surgical procedure.

Indications for use: Applied Medical's Inzii Ripstop Redeployable retrieval system is indicated for use as a receptacle for the collection and extraction of tissue, organs, and calculi during general and laparoscopic surgical procedures.

Comparison of Technological Characteristics with the Predicate Device

The subject device Inzii Ripstop Redeployable Retrieval System has the same indications for use as the predicate device Inzii Tissue Retrieval System. The subject device features a stronger Ripstop nylon bag and a change in design that allows it to be deployed multiple times.

The predicate device is packaged with the bag rolled up inside the tube. The predicate device is inserted into a trocar, the bag is deployed followed by the bag being cinched closed, the Introducer tube and trocar removed, and the bag with the specimen retrieved through the incision site.

The subject device is packaged with the bag outside of the tube. The bag must be retracted into the tube, followed by inserting it into the trocar and deployed to retrieve the specimen. If a surgeon deems it appropriate, the subject device can be redeployed multiple times in a single surgical procedure. For final deployment, the bag is cinched closed, the Introducer tube and trocar are removed, and the bag with the specimen is retrieved through the incision site. Table 1 below provide a side-by-side comparison of the predicate and subject device's attributes.

Table 1: Substantial Equivalency Comparison

Characteristics	Predicate Specimen Retrieval System K060051 (10mm, 15mm)	Ripstop Redeployable Retrieval System (10mm, 15mm)
Indications for use	The Applied Medical Inzii retrieval systems are indicated for use as receptacles for the collection and extraction of tissue, organs, and calculi during general and laparoscopic surgical procedures.	Same
System Design	A tubular structure that contains the bag in rolled up form. Activation of a mechanism deploys the bag into the body cavity. Supports automatically open the bag which can be detached from the deployment mechanism and cinched closed. Specimen bag can be reopened after it is cinched closed	A tubular structure with bag supplied in a deployed state. The bag is retracted into the introducer tube, followed by the activation of a mechanism that deploys the bag into the body cavity. Supports automatically open the bag to collect the sample. The bag can be deployed multiple times. This is followed by final deployment where the bag can be detached from the deployment mechanism and cinched closed. Specimen bag can be reopened after it is cinched closed.
Usage	Disposable single use	Same
Bag volume	225 ml	265 ml (10 mm model) 1600 ml (15 mm model)
Introducer tube outer diameter	10.2 mm	11.2 mm (10 mm model) 15.9 mm (15 mm model)
Working length	30 cm	32 cm (10 mm model) 47 cm (15 mm model)
Bag closure method	Cord loop	Same
Shelf life	36 months	Same
Materials	The specimen bag is made from polyurethane.	The specimen bag is made from Ripstop nylon.

	The introducer mechanism is made of various metal and polymer materials.	The introducer mechanism is made of same materials as the predicate and includes an additional adhesive.
Sterilization	Radiation sterilization (E-Beam)	Ethylene Oxide sterilization (EO)
Biocompatibility	Compliant with ISO 10993 series and 2020 FDA guidance document Use of International Standard ISO 10993-1, *"Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*	same
Compatibility with environment and other devices	Device is compatible with 10mm trocars or larger	The 10 mm device is compatible with 11mm trocars or larger. The 15 mm device is compatible with 15mm trocars or larger.
Standards met	There currently are no recognized performance standards for specimen retrieval systems of this type. For that reason, Applied Medical Resources Corporation constructed specific protocols and test methods to measure system performance to allow comparison with the predicate device. The test data confirmed equivalence in performance, safety, and efficacy between subject and predicate devices.	Same

Discussion of Performance Data

Performance testing included non-clinical bench tests and simulated use tests where the subject and predicate devices were tested side by side to demonstrate substantial equivalence. In addition to the tests covered per K060051, the strength of the Ripstop nylon bag was also demonstrated using an additional test performed in K100959, thus adding the model in scope of K100959, CD003 5mm Inzii Universal Retrieval System as a reference device. Applied Medical submits a predicate device and reference device to demonstrate substantial equivalence of the subject device.

The performance data includes a summary of test methods, sample size, acceptance criteria, and results. The following performance data were provided in support of the substantial equivalence determination.

- Specimen Retrieval System Functionality testing
- Specimen Retrieval System Leak testing
- Specimen Bag Closure testing
- Specimen Bag Tear Resistance Test
- Specimen Bag Strength testing
- Specimen Bag Pressure testing
- Specimen Bag Puncture testing

Biocompatibility testing: The subject device is intended to access body cavities and therefore will contact internal tissue systems. The exposure of these devices is limited and has a duration of contact with the body of up to 24 hr. When using the device according to its intended use, it is classified per EN ISO 10993-1; 2020 as follows:

- Externally Communicating Device
- Contacting Tissue/Bone/Dentin
- Limited Contact Duration

Based on the nature and duration of the device contact, the following biological endpoints were considered:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity (AST)
- Material Mediated Pyrogenicity (MMP)

Conclusion

Based on the intended use, technological characteristics, and performance testing results, the subject device is considered substantially equivalent to the predicate device.