November 10, 2021

Agency for Medical Innovations GmbH
% Allison C. Komiyama, Ph.D., R.A.C.
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Avenue, Suite B-257
San Diego, CA 92110

Re: K212659
Trade/Device Name: More-Cell-System
Regulation Number: 21 CFR§ 884.4050
Regulation Name: Gynecologic Laparoscopic Power Morcellation Containment System
Regulatory Class: II
Product Code: PMU
Dated: August 16, 2021
Received: August 23, 2021

Dear Allison C. Komiyama:

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)*
K212659

Device Name
More-Cell-System

Indications for Use *(Describe)*
More-Cell-System is intended for use as a tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue considered benign, resected during multi-site laparoscopic surgery for power morcellation and removal.
When used in women with fibroids, the More-Cell System is for women who are pre-menopausal and under age 50.
More-Cell-System is compatible with electromechanical laparoscopic power morcellators that are between 12 mm and 20 mm in shaft outer diameter and between 95 mm and 170 mm in shaft working length.

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

DATE PREPARED
November 8, 2021

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PROPRIETARY NAME OF SUBJECT DEVICE
More-Cell-System

COMMON NAME
Containment system, laparoscopic power morcellation, with instrument port

DEVICE CLASSIFICATION
Gynecologic laparoscopic power morcellation containment system
(21 CFR 884.4050, Product Code PMU, Class II)

PREDICATE DEVICE IDENTIFICATION

510(k) Number	*Predicate Device Name / Manufacturer*
K192898	PneumoLiner / Advanced Surgical Concepts

The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION
The More-Cell-System device is used as a receptacle for collection and extraction of tissue during laparoscopic surgical procedures (e.g., hysterectomy and myomectomy). The key components of the device include the following:

A. More-Cell Bag: A single use, insufflatable, transparent, EO sterilized bag made of 50 µm thick polyurethane film that is biocompatible and cell-tight. The bag includes printed lines to aid in visualization during surgery. There are two openings to the bag: one

opening that is 16 cm in diameter where a morcellator can be inserted (and where tissue can be removed), and a second opening that is 16 mm in diameter x 190 mm in length where a laparoscope can be inserted to visualize the surgical procedure. The bag capacity is 2.5 L (340 x 250 mm).

B. Visi-Shield: A metal sleeve with a polycarbonate window for lens protection (comes in 0° or 30° angle) that is cell-tight to protect the laparoscopic camera during a surgical procedure. Using the Visi-Shield the surgical procedure can be visualized without compromising the integrity of the bag, laparoscopic view, or safety of the laparoscopic camera.

The More-Cell-System functions in the following manner:

1. A first incision (suprapubic) is made and a surgical port is inserted using a port obturator. The port obturator is then removed.
2. The More-Cell Bag is introduced through the port into the abdomen.
3. The bag is unfolded inside the abdomen and is filled with the tissue that is to undergo morcellation.
4. The port is removed and the large opening of the bag is pulled out through the first incision where it had been introduced. The small opening of the bag is pushed through a second incision (umbilical).
5. A trocar port is inserted into the small opening of the bag towards the encased tissue. Through this port, the More-Cell Bag is insufflated with CO_2.
6. The optic that is encased in the Visi-Shield is inserted into the umbilical trocar port.
7. Through the large opening of the bag, a morcellator equipped with a blunt obturator is inserted towards the encased tissue. The tissue undergoes morcellation under visual control of the optic.
8. Following completion of morcellation, the morcellator, optic (including Visi-Shield), and umbilical trocar port are removed. The small opening is closed tightly by tying two (2) knots in the neck of the bag.
9. The More-Cell Bag is removed from the abdomen by grasping the bag at the large opening and withdrawing it through the first incision.

INDICATIONS FOR USE

More-Cell-System is intended for use as a tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue considered benign, resected during multi-site laparoscopic surgery for power morcellation and removal. When used in women with fibroids, the More-Cell System is for women who are pre-menopausal and under age 50.

More-Cell-System is compatible with electromechanical laparoscopic power morcellators that are between 12 mm and 20 mm in shaft outer diameter and between 95 mm and 170 mm in shaft working length.

COMPARISON OF INDICATIONS FOR USE

The predicate device includes the following indications for use:

The PneumoLiner device is intended 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-port laparoscopic surgery during power morcellation and removal. When used in women with fibroids, the PneumoLiner is for women who are pre-menopausal and under age 50. The PneumoLiner is compatible with bipolar or electromechanical laparoscopic power morcellators that are between 15mm and 18 mm in shaft outer diameter and 135mm and 180mm in shaft working length and which have an external component that allows for the proper orienation of the laparoscope to perform a contained morcellation.

The More-Cell-System indications for use differs from the predicate with respect to multi-site versus single-port surgery and the identification of compatible laparoscopic power morcellators. These differences in indications for use are based on the differences in design of the devices and the testing provided. More-Cell-System is intended for use during multi-site laparoscopic surgeries as it includes a second opening for optic insertion. This difference does not represent a new intended use as both devices are tissue containment systems to be used during minimally invasive gynecologic laparoscopic surgery. More-Cell-System is compatible with electromechanical laparoscopic power morcellators that are between 12 mm and 20 mm in shaft outer diameter and between 95 mm and 170 mm in shaft working length. The predicate 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. These differences do not represent a new intended use.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device has a similar design and dimensions and uses similar or identical materials as the device cleared in K192898. Unlike the predicate device, the More-Cell Bag has two openings to the bag: one opening where a morcellator can be inserted into the abdomen and where tissue can be removed, and a second opening where a laparoscope can be inserted to visualize the surgical procedure. A disposable laparoscopic camera sleeve called the Visi-Shield is used on the laparoscope in order to protect it against any cell contamination during the surgical procedure. The subject device has a lined pattern printed on the bag while the predicate has a grid pattern. After the tissue is removed from the abdomen, the outer part of the second opening is everted and knotted. This technique is intended to keep any residual contamination during the morcellation process from being introduced to the abdominal cavity during bag removal. The subject device is provided sterile using EO sterilization and has a shelf life of 2 years, whereas the predicate device is gamma irradiated and has a shelf life of 3 year.

General Device Characteristics	Subject Device K212659	Predicate Device K1928998
Design	Tissue retrieval pouch with two openings: large opening for morcellator and small side opening for laparoscope	Tissue retrieval pouch with single opening with boot assembly for insertion of morcellator and laparoscope
Size/Capacity	Length: 340 mm Width: 250 mm Volume: 2.5 L	Length: 499.50 mm Width: 350 mm Volume: 10.58 L
Opening Dimensions	16 cm diameter (large opening) 16 mm diameter (small opening)	16 cm diameter
Bag removal method	Small opening knotted, pulled into the abdomen and entire bag removed through umbilical incision	Bag removed through umbilical incision
Insufflation required	Yes	Yes
Bag Materials	Polyurethane bag with polyester thread, stainless steel bracket/rivet, silicone and ink	Polyurethane bag with nylon tether/tabs, nitinol opening ring and ink
Optic Sleeve	Yes (Visi-Shield)	No
Optic Sleeve Materials	Stainless steel, polycarbonate and silicone	N/A
LPM Compatibility	Electromechanical LPMs of specific dimensions	Bipolar and electromechanical LPMs of specific dimensions
Sterility	EtO	Gamma Radiation
Packaging	Tyvek pouch	Tyvek pouch
Shelf Life	2 yrs	3 yrs

The differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The following non-clinical testing has been performed on the More-Cell-System to demonstrate substantial equivalence to the predicate devices:

- Sterilization validation per ANSI/AAMI/ISO 11135 and ISO 10993-7
- Shelf life validation for 2-years utilizing samples that have undergone accelerated aging, shipping and handling including:

- Per ASTM F1980 and ISO 11607, package integrity included visual inspection, dye penetration test, peel strength test and microbiological stability
- Device functionality

- Biocompatibility testing:
  The biocompatibility evaluation for the More-Cell-System was conducted in accordance with the FDA biocompatibility guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," issued September 4, 2020. The More-Cell-System is categorized as an externally communicating device, contacting tissue/bone/dentin for a limited duration <24 hours. The following tests were conducted:
  - Cytotoxicity per ISO 10993-5
  - Sensitization per ISO 10993-10
  - Intracutaneous irritation per ISO 10993-10
  - Acute systemic toxicity per ISO 10993-11

  Testing demonstrated the device was not cytotoxic, sensitizing, irritating or acutely toxic.
- Performance testing (bench):
  - Impermeability testing was conducted on 36 More-Cell bags that had previously been exposed to 2-years of aging and simulated use conditions. Impermeability to E. coli was evaluated using an immersion test. More-Cell bags were subjected to pressures intended to represent worst-case clinical conditions). Positive and negative controls were included. There was no evidence of permeability in the test samples and the positive and negative controls performed as intended. This sample size was adequate to demonstrate a failure rate of less than 90% with a Type 1 error rate of 0.025 and power of 90%.
  - The following tests were conducted on 30 samples each that had undergone two years of simulated aging (with the exception of the rivet testing). This sample size was adequate to demonstrate that the acceptance criteria were met with a 95% confidence interval and a significance level of 0.05. Acceptance criteria were developed based on testing evaluating the forces that the device will be subjected to during clinical use.
    - Puncture resistance testing
    - Insufflation pressure (burst) testing
    - Material strength testing of polyurethane bag
      - Tensile testing of the sleeve with knots
      - Weld seam in sleeve
      - Sleeve/bag junction
      - Tensile strength of bag opening
      - Rivet connections at bag opening

- Eyelet tabs used for grasping
- Weld seam in bag
- Weld seam at neck of the bag

▪ Visi-Shield performance

- Friction force
- Bond strength
- Demonstrate the Visi-Shield component does not adversely affect the optical performance of the laparoscope or the user's visualization of the operating field

- Performance testing (animal):
  - The More-Cell-System was tested in an *in vivo* porcine model. Two surgeons performed laparoscopic supracervical hysterectomy on 16 animals randomly distributed into two groups: in group A (n = 8), power morcellation (using three different electromechanical morcellators) and tissue extraction were performed using the More-Cell-System (''MCS group''), and in group B (n = 8) the same operation was performed conventionally without a tissue retrieval bag (''control group''). Overall surgery time was prolonged in the bag group by 12.86 min (p = 0.0052; 95 % confidence interval 4.64 to 21.07). No disseminated myometrial (uterine wall) cells were found in the peritoneal washings of the abdominal cavities from the animals in group A. However, positive cytology was found in five of eight cases in the control group B (p = 0.0256). A visual examination of the 8 More-Cell-Bags after morcellation with dye and another with pressurized air while submerged in water following after removal did not show evidence of a breach.

SUMMARY OF CLINICAL TESTING

- Usability studies:
  - An observational study was conducted outside the US to evaluate usability of the More-Cell-System in women undergoing laparoscopic gynecologic morcellation. Twenty six clinical cases were performed by 26 surgeons (Austria, n=6; Germany, n=19; Switzerland, n=1) at 22 sites with various levels of experience and using a wide range of morcellators, Training was limited to a review of the Instructions for Use before the surgeon performed the procedure. Surgeons were asked to evaluate and record the ease of bag insertion and removal, the time to insert the bag and total operating time, the ease of instrument insertion and removal, the ease of placing a tissue specimen inside the bag, the ability to maintain adequate distension of the bag, the ability to maintain adequate inflation of the bag at various pressures, the ability to see inside the bag using the Visi-Shield, the size evaluation of tissue specimen, whether the morcellator blade made contact with the bag wall, whether the accompanying surgical instruments damaged the bag, whether the bag was removed laparoscopically without spilling the contents, and

the type of morcellator used. After the 26 cases, the bags were filled with blue fluid to evaluate if any leaks could be detected. Procedures were successfully carried out with pass-criteria satisfied and no leaks observed. No significant differences were noted based on surgeon experience, specimen size or morcellator used. With no failures noted in 26 tests, an overall acceptance criteria of 87.5% reliability is met with a 95% confidence interval.

- A simulated use study was conducted with 11 U.S. surgeons with a range of laparoscopic surgery experience (2.5 years to 30 years) to ensure that representative users can perform the critical tasks associated with the More-Cell-System and comprehend the procedural safety information. Participants were provided with the training materials, which includes a copy of the Instructions for Use and Surgery Quick Guide Instruction training videos. After review of these materials there was a one hour break. The participants then performed a simulated use on a pelvic trainer model. They were observed to assess adherence to critical tasks. Participants completed two questionnaires to assess knowledge tasks and adequacy of device usage, and participated in group interviews for comments and open feedback from users. No use errors were found during testing. The information provided in the questionnaires demonstrated adequate comprehension of the procedural tasks to ensure safe use of the device and positive feedback on ease of device use.

These usability studies demonstrate that no additional training beyond review of labeling and videos is necessary for proper device use.

CONFORMANCE TO SPECIAL CONTROLS

The More-Cell-System conforms to the following special controls:

1. The patient-contacting components of the device have been demonstrated to be biocompatible.
2. Device components that are labeled sterile have be validated to a sterility assurance level of 10^{-6}.
3. Performance data support shelf life by demonstrating continued sterility of the device and sterile components, package integrity, and device functionality over the intended shelf life.
4. Non-clinical performance data demonstrate that the device meets design specifications and performance requirements. The following performance characteristics have been 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 has been developed and validated to ensure users can follow the instructions for use.
6. Labeling includes:
   - Contraindication for use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
   - 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.
     Note: The language of this contraindication was revised during the review of the predicate device for clarity. The labeling for the More-Cell-System is consistent with the predicate device and identifies the contraindication as follows: "Do not use for removal of uterine tissue containing suspected fibroids in patients who are: post- menopausal or over 50 years of age; or candidates for en-bloc tissue removal 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.

CONCLUSION

The subject device has the same intended use as the predicate device. Differences in the indications for use statement do not alter the intended use. Technological differences between the subject and predicate device do not raise different questions of safety and effectiveness. The subject device has been shown to meet the special controls associated with this product type which included labeling requirements. The testing performed, including biocompatibility, sterilization and shelf life validation, non-clinical performance testing, and clinical testing, supports that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate.