October 31, 2025

Applied Medical Resources Corp.
Derek Greene
Regulatory Affairs Associate Principal Specialist
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K252442
Trade/Device Name: Kii Structural Balloon Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 1, 2025
Received: August 4, 2025

Dear Derek Greene:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.31 10:50:20 -04'00'

Colin Kejing Chen
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252442

Please provide the device trade name(s).

Kii Structural Balloon Access System

Please provide your Indications for Use below.

Kii Structural Balloon Access System is indicated for use in patients undergoing laparoscopic surgery requiring a path of entry and/or tissue retraction of the extraperitoneal space.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

510(k) #: K252442

Contact Details

Applicant Name	Applied Medical Resources Corp.
Applicant Address	22872 Avenida Empresa Rancho Santa Margarita CA 92688 United States
Applicant Contact Tel.	949-713-8009
Applicant Contact	Dr. Derek Greene
Applicant Contact Email	derek.greene@appliedmedical.com
Preparation Date	30 October 2025

Device Name

Device Trade Name	Kii Structural Balloon Access System
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Name	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name	Product Code
K942636	Auto Suture Structural Balloon Trocar	GCJ
K060096	Modular Trocar System (reference device)	GCJ
K182024	Dissecting Balloon System (reference device)	GCJ

Device Description Summary

Applied Medical's Kii Structural Balloon Access System provides a path of entry and/or tissue retraction for laparoscopic procedures in the extraperitoneal space. The system is provided sterile.

The system is composed of four main components:

- An obturator that facilitates insertion of the system through an incision.
- A cannula with bolster and attached balloon, encased within a perforated sheath.
- A seal which maintains insufflation.
- An inflation bulb that is used to manually inflate and deflate the balloon.

510(k) Summary

Intended Use/Indications for Use

Kii Structural Balloon Access System is indicated for use in patients undergoing laparoscopic surgery requiring a path of entry and/or tissue retraction of the extraperitoneal space.

Indications for Use Comparison

The indications for use of the subject and predicate device systems contain minor differences, which do not change the intended use of the device. Both contain an indication for the same essential function of the device to allow the passage of laparoscopic instrumentation through the device, with the subject referring to this as a "path of entry" and the predicate referring to this as a "sealed port of access". The predicate device includes indications for patients undergoing laparoscopic surgical procedures, as well as patients undergoing laparoscopic surgery in extraperitoneal procedures. The subject device utilizes a subset of those indications, only referencing to patients undergoing laparoscopic surgery of the extraperitoneal space. The indications of the predicate device list specific procedural examples that may take place within the extraperitoneal space. The indications of the subject device do not explicitly list example procedures, however it can be used within those outlined in the indications of the predicate device.

Technological Comparison

The subject and predicate device systems are both structural balloon trocars intended to provide access as a port of entry for laparoscopic instrumentation and retract tissue in the extraperitoneal space. Both systems contain an obturator and cannula. Both obturators have a blunt tip to aid in insertion of the device. Both cannulas contain a bolster mechanism, which inhibits trocar migration and seals for insufflation, and balloon inflation port that is compatible with an inflation bulb. Both cannulas contain an "A-frame" balloon that is encased within a perforated sheath that opens and remains anchored to the cannula as the balloon is inflated with the inflation bulb. Both systems contain a seal mechanism, which interfaces with insufflation tubing and maintains insufflation with and without instruments inserted.

510(k) Summary

The subject device system has minor differences from the predicate device. The seal mechanism of the subject device is detachable, while the predicate device is affixed to the cannula. The materials and components of the seal and bolster of the subject device are different from the predicate; however, they perform the same core function. Lastly, the inflation bulb to be used with the subject device is provided separately (as part of the Kii Dissecting Balloon, cleared within K182024), whereas it is provided within the same packaging of the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-clinical tests:

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

Biocompatibility

The biocompatibility evaluation for the Brand X device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "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," as recognized by FDA. The structural balloon device is considered tissue contacting for a duration of less than 24 hours, therefore the following testing was performed:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogen Testing

Functional Performance

Testing was conducted to verify that the subject device met all design specifications and performed equivalent to the predicate device. Benchtop testing assessed functional performance of the structural balloon device and included the following:

- Simulated Use Tests
- Balloon Dimensional Comparison
- Bolster Leak Test

510(k) Summary

- Balloon Burst Test

Sterility
Testing was conducted to validate the sterilization of the device to a SAL of 10^-6. Testing was conducted in compliance with: ANSI AAMI ISO 13004: 2022, ANSI AAMI ISO 11137: 2006/(R)2015, ISO 11137-2 Third edition 2013-06 [Including AMD1:2022], ANSI AAMI ISO 11137-3: 2017(R)2023, ISO 11737-1 Third edition 2018-01 [Including AMD1:2021], and ANSI AAMI ISO 11737-2: 2019

Shelf-Life
Testing was performed to qualify the subject device for a 36-month shelf life. Testing was conducted in compliance with: ASTM F1980;2021, ASTM F88/F88M-15;2023, and ASTM F1929;2023.

Clinical tests:

Not Applicable. Clinical data were not required to support the safety or effectiveness of the subject device.

Conclusion:

The results of the testing demonstrated that the subject Kii Structural Balloon Access System is substantially equivalent to the currently marketed predicate Auto Suture Structural Balloon Trocar for the same intended use. The non-clinical testing is sufficient evidence for the safety and efficacy of the subject device for its indications for use.