February 23, 2026

Applied Medical Resources Corporation
Apeksha Shanbhag
Senior Manager, Regulatory Affairs
22872 Avenida Empresa
Rancho Santa, California 92688

Re: K253531
Trade/Device Name: Alexis® Lighted Wound Protector-Retractor, Rigid, Medium (CL402); Alexis® Lighted Wound Protector-Retractor, Flexible, Medium (CL302)
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: KGW, FTF
Dated: November 12, 2025
Received: November 13, 2025

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 (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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.02.23 15:56:41 -05'00'

for Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253531

Device Name
Alexis® Lighted Wound Protector-Retractor, Rigid, Medium (CL402); Alexis® Lighted Wound Protector-Retractor, Flexible, Medium (CL302)

Indications for Use *(Describe)*
The Alexis Lighted Wound Protector-Retractor is a device that allows the surgeon to access the abdominal cavity through an atraumatically retracted wound, providing maximum exposure with minimum incision size. In addition to incision retraction, it is intended to provide supplemental illumination and protect against wound contamination during both laparoscopic and open surgery. The Alexis Lighted Wound Protector-Retractor is capable of temporarily closing an incision to maintain pneumoperitoneum during laparoscopic surgery, or to serve as an additional trocar port site. In addition, the device may be used to access the thoracic cavity or other soft tissue retraction during cardiac and general 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.

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Applied Medical
A New Generation Medical Device Company

510(k) Summary

510(k) #: K253531

Contact Details

Applicant Name	Applied Medical Resources Corp.
Applicant Address	22872 Avenida Empresa Rancho Santa Margarita CA 92688 United States
Applicant Contact Tel.	949-713-8341
Applicant Contact	Apeksha Shanbhag
Applicant Contact Email	apeksha.shanbhag @appliedmedical.com
Date Prepared	20 February 2026

Subject Device

Device Trade Name	Alexis® Lighted Wound Protector-Retractor
Common Name	Lighted Wound Protector and Retractor
Product Classification	KGW (21CFR 878.4370, Surgical Drape And Drape Accessories) FTF (21CFR 878.4580, Surgical lamp)

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name	Product Code
K041711	Alexis Wound Retractor (Primary Predicate)	KGW
K840372	Surch-Lite FLEXIBLE ILLUMINATOR 15" (Secondary Predicate)	FTF

Device Description Summary

Applied Medical's Alexis Lighted Wound Protector-Retractor provides wound protection and retraction during laparoscopic and open surgery while providing supplemental illumination. The device is provided sterile, and the reusable power supply is provided non-sterile. The device and power supply are used in the clinical setting.

The system includes five main components:

- A sheath that protects the wound and provides retraction with tension applied.
- An outer ring that is rolled to create tension on the sheath and anchor the device.
- An inner ring with embedded LEDs that anchors the device and provides illumination.
- A power cord that connects to the reusable power supply.
- A reusable power supply that connects to a grounded receptable to provide power to the LEDs.

Intended Use/Indications for Use

The Alexis Lighted Wound Protector-Retractor is a device that allows the surgeon to access the abdominal cavity through an atraumatically retracted wound, providing maximum exposure with minimum incision size. In addition to incision retraction, it is intended to provide supplemental illumination and protect against wound contamination during both laparoscopic and open surgery. The Alexis Lighted Wound Protector-Retractor is capable of temporarily closing an incision to maintain pneumoperitoneum during laparoscopic surgery, or to serve as an additional trocar port site. In addition, the device may be used to access the thoracic cavity or other soft tissue retraction during cardiac and general surgical procedures.

Indications for Use Comparison

The subject device is a multiple function device. The intended use and principles of operation for the subject device and predicate devices are the same with differences in wording.
The indications for use of the subject and primary predicate device contain minor differences that do not change the intended use of the device. Additionally, the primary predicate device has different sizes, but the indications of the subject device are aligned with the predicate's equivalent model variant (medium).

The indications for use of the subject and secondary predicate device are slightly different. Both devices include supplemental illumination as an indication. The devices are considered substantially equivalent because the illumination feature of the subject device falls under a "tool type indication" per "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" 2014.

Contraindications Comparison

The subject device has no contraindications while the primary predicate and secondary predicate have contraindications. The primary predicate has a general statement related to surgeons using their best judgement when using the device. This is considered unnecessary for the subject device as surgeons should always use their best judgment when determining what devices are safe for use.

The secondary predicate has a contraindication related to use of the device in the presence of flammable substances or materials, and the subject device has no contraindications. The subject device addresses flammability risks in the Warnings section of the IFU per the standard warnings for medical electrical devices listed in IEC 60601-1.

Technological Comparison

The subject and primary predicate device share the same general design intended to provide wound protection and retraction. Both devices contain a sheath, an outer ring and an inner ring made of the same material. The subject and primary predicate device are substantially equivalent in functionality with the exception of the supplemental illumination function.

Both subject and secondary predicate devices provide supplemental illumination to the surgical site. The secondary predicate device achieves this through a filament bulb at the distal end of a flexible shaft powered by battery, while the subject device utilizes embedded LEDs within its inner ring and is mains powered through the use of a reusable accessory (power supply). Although there are differences in technological characteristics, the subject device has been evaluated against IEC 60601-1 and IEC 60601-1-2, for its electrical, mechanical, and thermal safety, and designed in consideration with and IEC 62471 for photobiological safety. The subject device can provide clinically relevant supplemental illumination as established through secondary predicate device 510k.

Performance Testing

Non-clinical Performance Testing:

The following non-clinical tests were conducted to support substantial equivalence:

Biocompatibility

- The biocompatibility evaluation for the Alexis Lighted Wound Protector-Retractor 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 recommended by FDA. The subject device is considered tissue contacting for a duration of less than 24 hours, therefore the following testing was performed:

ANSI/AAMI/ISO 10993-5:2009 - Cytotoxicity – MEM Elution Test
ISO 10993-10:2021 - Maximization Test for Delayed-Type Hypersensitivity in Hartley Guinea Pigs
ISO 10993-23:2021/Amend 1:2025 - Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits
ISO 10993-11:2017 - Acute Systemic Toxicity in Mice
USP, General Chapter <151> - USP Rabbit Pyrogen Study, Material Mediated

- **Electromagnetic Compatibility (EMC) and Immunity Testing**
  The subject device was tested in accordance with applicable standards from the IEC 60601 series to ensure compliance with electromagnetic compatibility and immunity requirements.
  Emission testing was conducted under the following standards:
  - IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION (60601-1-2:ed4.0:2014 + AMD1:2020)
  - ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
  - IEC CISPR 11: ed6.0:2015 + AMD1:2016 + AMD2:2019

  Immunity testing was conducted under the following standards:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION (60601-1-2:ed4.0:2014 + AMD1:2020)
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]

- **Electrical, Mechanical, Thermal and Optical Radiation Safety Testing**
  The subject device was evaluated for electrical, mechanical, and thermal safety under the following standards:
  - IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION (60601-1:ed3.0:2005 + AMD1:2012 + AMD2:2020)
  - ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
  - IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION (60601-1-6:ed3.0:2010 + AMD1:2013 + AMD2:2020)
  - IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION (60601-1-2:ed4.0:2014 + AMD1:2020)
  - ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
  - IEC CISPR 11: ed6.0:2015 + AMD1:2016 + AMD2:2019

  The subject device was designed in consideration of IEC 62471:2006 for optical radiation safety.

- **Functional Performance Testing**
  Testing was conducted to verify that the subject device met all design specifications and performed equivalent to the predicate devices. Benchtop testing assessed functional performance of the subject device and included the following:
    - Supplemental Illumination
    - Prolonged Circumferential Retraction
    - Incision Site Anchoring
    - Trocar Port Site Insufflation
    - Insertion and Removal Cycling
    - Viral Penetration Testing

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 Alexis Lighted Wound Protector-Retractor is substantially equivalent to the currently marketed predicates, Alexis Wound Protector-Retractor (primary), and Surch-Lite (secondary) 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.