April 24, 2026

Applied Medical Resources Corporation
% Apeksha Shanbhag
Official Correspondent
Applied Medical Resources Corporation
Contact Address

Re: K260982
Trade/Device Name: Alexis Lighted Wound Protector-Retractor, Flexible, Extra small (CL312); Alexis Lighted Wound Protector-Retractor, Flexible, Small (CL301);Alexis Lighted Wound Protector-Retractor, Flexible, Large (CL303); Alexis Lighted Wound Protector-Retractor, Rigid, Small (CL401);Alexis Lighted Wound Protector-Retractor, Rigid, Large (CL403);Alexis Lighted Wound Protector-Retractor, Rigid, Medium (CL402); Alexis Lighted Wound Protector-Retractor Rigid, Medium (CL302)

Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: KGW, FTF
Dated:March 25, 2026
Received: March 25, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Tanisha Hithe

Digitally signed by Tanisha Hithe
Date: 2026.04.24 16:31:12 -04'00'

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

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.	K260982

Please provide the device trade name(s).

Alexis Lighted Wound Protector-Retractor, Flexible, Extra small (CL312);
Alexis Lighted Wound Protector-Retractor, Flexible, Small (CL301);
Alexis Lighted Wound Protector-Retractor, Flexible, Large (CL303);
Alexis Lighted Wound Protector-Retractor, Rigid, Small (CL401);
Alexis Lighted Wound Protector-Retractor, Rigid, Large (CL403);
Alexis Lighted Wound Protector-Retractor, Rigid, Medium (CL402);
Alexis Lighted Wound Protector-Retractor, Rigid, Medium (CL302)

Please provide your Indications for Use below.

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 small and medium Alexis lighted wound protector-retractors are capable of temporarily closing an incision to maintain pneumoperitoneum during laparoscopic surgery, or to serve as an additional trocar port site. In addition, indicated sizes may be used to access the thoracic cavity or other soft tissue retraction during cardiac and general surgical procedures.

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

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

Applied Medical
A New Generation Medical Device Company

510(k) Summary

510(k) #: K260982

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	22 April 2026

Subject Device

Device Trade Name	Alexis Lighted Wound Protector-Retractor, Flexible, Extra small (CL312); Alexis Lighted Wound Protector-Retractor, Flexible, Small (CL301);Alexis Lighted Wound Protector-Retractor, Flexible, Large (CL303); Alexis Lighted Wound Protector-Retractor, Rigid, Small (CL401);Alexis Lighted Wound Protector-Retractor, Rigid, Large (CL403);Alexis Lighted Wound Protector-Retractor, Rigid, Medium (CL402); Alexis Lighted Wound Protector-Retractor Rigid, Medium (CL302)
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
K253531	Alexis® Lighted Wound Protector-Retractor	KGW, FTF

Device Description Summary

Applied Medical's Alexis Lighted Wound Protector-Retractors (sizes: Extra Small, Small, Medium and Large) provide 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 subject device includes the following 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 tether and tether tag attached to the inner ring to facilitate removal from the incision (included on model variants CL312, CL301 & CL401 only).
- 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.

Subject Device Specifications

Model	Size	Incision Size	Outer Ring	Wound Retraction	Illumination	Thoracic Retraction	Maintain Insufflation	Trocar site	Tether & tether tag
CL312	Extra small	2 – 4cm	Flexible	✓	✓	✓	NA	NA	✓
CL301	Small	2.5 – 6cm	Flexible	✓	✓	✓	✓	✓	✓
CL302	Medium	5 – 9cm	Flexible	✓	✓	✓	✓	✓	NA
CL303	Large	9 – 14cm	Flexible	✓	✓	NA	NA	NA	NA
CL401	Small	2.5 – 6cm	Rigid	✓	✓	✓	✓	✓	✓
CL402	Medium	5 – 9cm	Rigid	✓	✓	✓	✓	✓	NA
CL403	Large	9 – 14cm	Rigid	✓	✓	NA	NA	NA	NA

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 small and medium Alexis lighted wound protector-retractors are capable of temporarily closing an incision to maintain pneumoperitoneum during laparoscopic surgery, or to serve as an additional trocar port site. In addition, indicated sizes 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 and predicate devices are multiple function devices. The intended use and principles of operation for the subject and predicate devices are the same.

With the exception of the small variant of the subject device, which has the same indications as the predicate device, the subject device's indications for use are a subset of the predicate device's indications for use. The subject device variants do not introduce any additional indications for use as compared to the predicate device. The extra small and large model variants of the subject device are not intended to be used to maintain pneumoperitoneum or as an additional trocar port site. Furthermore, the large model variant is not intended to be used in the thoracic cavity. The described differences in indications between different sizes exist because there is no clinical need for certain variants to have the full scope of indications.

Size	Wound Retraction	Thoracic Retraction	Maintain Pneumoperitoneum	Trocar Site
Predicate device				
M	✓	✓	✓	✓
Subject device				
XS	✓	✓	NA	NA
S	✓	✓	✓	✓
M	✓	✓	✓	✓
L	✓	NA	NA	NA

Contraindications Comparison

There are no differences in contraindications.

Technological Comparison

The predicate device is medium size, while the subject device is available in extra small, small, medium and large sizes. Additionally, the predicate device is designed with either a rigid or flexible outer ring. The small, medium and large subject devices are available with both outer rings, while the extra small is only available with a flexible outer ring variant. The extra small and small sizes include a tether and tether tag to facilitate removal of the retractor from the incision. The biocompatibility of the tether and tether tag has been assessed in accordance with the ISO 10993-1 series of standards.

Performance Testing

Non-clinical Performance Testing:

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

- **Biocompatibility**
  The biocompatibility evaluation for the subject device 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," as recommended by FDA. The subject device is considered tissue contacting with a duration of less than 24 hours. The following testing was performed:
  - ISO 10993-5:2009 – Cytotoxicity – Cytotoxicity Study Using the ISO Elution Method

  The following standards were addressed through legally marketed devices (K253531 & K191294) since the device components in material and processing are identical.
  - 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 evaluated for electrosurgical compatibility in accordance with the applicable requirements of IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION (60601-1-2:ed4.0:2014 + AMD1:2020) and IEC 60601-1-2:2014 [Including AMD 1:2021].

  The following tests were performed on the subject device:

  - CISPR 11: 2015/AMD1:2016/AMD2:2019 - Radiated Emissions
  - CISPR 11: 2015/AMD1:2016/AMD2:2019 - Conducted Emissions
  - IEC 61000-3-2:2005/AMD1:2008/AMD2:2009 - Harmonic Current Emissions
  - IEC 61000-3-3:2013 - Voltage Fluctuations and Flicker
  - IEC 61000-4-2:2008 - Electrostatic Discharge (ESD)
  - IEC 61000-4-4:2012 -Electrical Fast Transients and Bursts (EFT)
  - IEC 61000-4-6:2013 - Conducted Immunity

  The following tests were addressed through the predicate device since the core circuitry, and the AC power accessory remain unchanged.

  - IEC 61000-4-3:2006/AMD1:2007/AMD2:2010 - Radiated RF Electromagnetic Field and Radiated Immunity – Proximity Fields from RF Wireless Communications
  - IEC 61000-4-3:2006/AMD1:2007/AMD2:2010 - Radiated Immunity – 5G-NR FR1 and 5G-NR FR2
  - IEC 61000-4-8:2009 - Power Frequency Magnetic Field Immunity
  - IEC 61000-4-39:2017 - Magnetic Field Immunity – WPT Immunity – WPT-EV
  - IEC 61000-4-5:2014 /AMD1:2017 - Surge Immunity
  - IEC 61000-4-11:2004/AMD1:2017 - Voltage Dips, Short Interruptions, and Voltage Variations

- **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 passed the established test methods, which demonstrates substantial equivalence to predicate device. 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 was not required to support the safety or effectiveness of the subject device.

Conclusion

The results of the testing demonstrated that the subject device, Applied Medical's Alexis Lighted Wound Protector-Retractor (sizes: Extra Small, Small, Medium and Large), is substantially equivalent to the predicate, Applied Medical's Alexis Lighted Wound Protector-Retractor (size: Medium) 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.