October 6, 2025

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

Re: K243152
Trade/Device Name: GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: Class II
Product Code: HEW

Dear Apeksha Shanbhag:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 2, 2025. Specifically, FDA is updating this substantial equivalence (SE) Letter to correct the official correspondent as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jason Roberts, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, Jason.Roberts@fda.hhs.gov.

Sincerely,

Jason Roberts -S

Jason Roberts
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

October 1, 2025

Applied Medical Resources Corp.
David Yu
Senior Specialist Regulatory Affairs
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K243152
Trade/Device Name: GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: II
Product Code: HEW
Dated: January 9, 2025
Received: September 5, 2025

Dear David Yu:

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: The Center for Devices and Radiological Health (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, The Food and Drug Administration (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,

Jason Roberts -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243152

Device Name
GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device

Indications for Use *(Describe)*
The GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device is intended to be inserted transvaginally to establish a path of entry for minimally invasive instruments and maintain insufflation during laparoscopic-assisted and vaginal gynecological procedures. The device may be used for sentinel pelvic lymph node dissection occurring in the retroperitoneal space. The device is also a conduit for the extraction of specimens

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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510(k) Summary

GelPoint V-Path Transvaginal Access Platform with Retroperitoneal Access Device

K243152

510(K) Submitter:	Applied Medical Resources Corp. 22872 Avenida Empresa Rancho Santa Margarita, CA, 92688 (949) 713-8000
Contact Person:	Apeksha Shanbhag Regulatory Affairs Senior Manager Applied Medical Resources Corp. apeksha.shanbhag@appliedmedical.com Tel: (949) 713-8341 Fax: (949) 713-8205
Date of Preparation:	October 1, 2025
Trade Name:	GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device
Common Name:	Transvaginal endoscopic surgery access port
Classification:	Regulation: 21 CFR 884.1640, Culdoscope & Accessories Device Class: Class II Product Code: HEW
Predicate Device:	Trade Name: Transvaginal Access Platform 510(k) #: K191294 Product Code: HEW No design-related recalls for the predicate device have been identified.

Device Description: The GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device consists of an intraperitoneal Alexis retractor and retroperitoneal Alexis retractor that are placed transvaginally to create a pathway to the peritoneum and retroperitoneum. A GelSeal cap attaches to the retractors at the opening of the vagina. The cap allows for insufflation and smoke evacuation. Sleeves inserted through the cap allow for passage of 5mm to 12mm laparoscopic instrumentation. Visualization is achieved via introduction of an endoscope through a sleeve. The device is provided sterile.

Indications for use: The GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device is intended to be inserted transvaginally to establish a path of entry for minimally invasive instruments and maintain insufflation during laparoscopic assisted and vaginal gynecological procedures. The device may be used for sentinel pelvic lymph node dissection occurring in the retroperitoneal space. The device is also a conduit for the extraction of specimens.

Comparison of Technological Characteristics with the Predicate Device

General Device Characteristics	**Predicate Device: Transvaginal Access Platform K191294**	**Subject Device: GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device**
Device Design	The platform facilitates access for gynecological procedures. The device consists of a retractor that is placed transvaginally. A GelSeal cap attaches to the retractor at the opening of the vagina. The cap allows for insufflation and smoke evacuation. Sleeves inserted through the cap allow for passage of laparoscopic instrumentation. Visualization is achieved via introduction of an endoscope through a sleeve. Gel technology allows for triangulation of instrumentation. Specimens can be retrieved by removing the GelSeal cap.	Same

Anatomical Sites	Vagina, pelvic, and peritoneal cavity	Vagina, pelvic, peritoneal cavity, and retroperitoneal cavity
Placement	Transvaginally	Same
Visualization Capability	Visualization is achieved via introduction of an endoscope through a sleeve.	Same
Expansion of Surgical Space	Utilizes CO2 insufflation via an insufflator (not included with device) connected to insufflation port on the device	Same
Device Removals	The flexible Alexis retractor features a tether attached to the inner ring of the device. The tether and tether tag are positioned outside of the patient during device placement and usage. To remove the retractor, the outer ring is first unrolled until the retractor becomes loose. The tether is then pulled to remove the inner ring from the pelvic cavity and the entire retractor from the vaginal canal.	Same
Materials	Polycarbonate, polyester, polyethylene, polyisoprene, silicone, stainless steel, nylon, polyurethane, thermoplastic elastomer	Same
Sterilization	Ethylene Oxide, Sterility Assurance Level of 10^{-6} Single use device; device is discarded after use	Same

There are no different questions of safety and effectiveness that arise from the differences in technology. The technological differences between GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device and the predicate device can be evaluated through performance testing and do not alter the intended use of the GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device.

The subject and predicate device have the same intended use, namely:

- To be inserted transvaginally,
- To allow passage of minimally invasive instruments for the purpose of visualizing gynecological organs, and
- To allow for diagnostic and operative gynecological procedures including the extraction of specimens.

Discussion of Performance Data

There are currently no performance standards related to transvaginal endoscopic ports; therefore, Applied Medical designed a protocol to evaluate and compare the predicate and subject device's ability to achieve key performance specifications, namely:

- Maintenance of transvaginal access
- Facilitation of instrument access to surgical site
- Maintenance of insufflation
- Retention
- Device removal

The testing confirms that the GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device has the ability to establish and maintain a path of entry for minimally invasive instruments and can remain anchored in the patient while withstanding conditions under normal clinical use. The testing also confirms that the integrity and sealing capability of the device system are adequate to maintain insufflation as a means to provide visualization of the surgical space. Lastly, device removal was assessed to ensure the retractor component of the subject device can safely be removed from the surgical space while remaining intact. Based on the results of the performance testing conducted, the subject device, GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device is considered substantially equivalent to the predicate, Transvaginal Access Platform, in terms of performance and does not raise any additional concerns of safety and effectiveness.

Biocompatibility

Biocompatibility studies were performed in accordance with the 2020 FDA guidance document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and "testing" as follows:

- Cytotoxicity: ISO 10993-5:2009
- Sensitization: ISO 10993-10:2010
- Irritation: ISO 10993-10:2010
- Acute Systemic Toxicity: ISO 10993-11:2017
- Pyrogenicity Potential: USP <151>, ISO 10993-11:2017

The biocompatibility test results demonstrate the GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device is biocompatible. The results show the subject device has met the criteria to be classified as a non-cytotoxic, non-sensitizer, non-irritant device that shows no sign of being systemically toxic or pyrogenic. The information provided for biocompatibility testing indicate the subject device is acceptable to demonstrate substantial equivalence from a biocompatibility standpoint.

Shelf-Life

The GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device has a shelf life of 3 years when packaged in Tyvek and nylon film pouches, in accordance

with the results of accelerated aged stability studies. Results from testing demonstrated that the devices could maintain their specifications over the stated shelf-life duration.

Clinical Performance Data

Baekelandt, J., Jespers, A., Huber, D., Badiglian-Filho, L., Stuart, A., Chuang, L., ... & Burnett, A. (2024). vNOTES retroperitoneal sentinel lymph node dissection for endometrial cancer staging: First multicenter, prospective case series. *Acta Obstetricia et Gynecologica Scandinavica*. (N=64)

Comba, C., Karakas, S., Erdogan, S. V., Demir, O., Şimşek, E., Karasabanoglu, F., ... & Ozdemir, I. A. (2024). Transvaginal natural orifice transluminal endoscopic surgery (VNOTES) retroperitoneal sentinel lymph node BIOPSY compared with conventional laparoscopy in patients with endometrial cancer. *Surgical Oncology*, *55*, 102099. (Group 1 N=19, Group 2 N=38)

Burnett, A. F., Huber, D. E., Chuang, L., & Baekelandt, J. F. (2023). 10061 vNOTES Sentinel Lymph Node Dissection for Gynecologic Malignancies. *Journal of Minimally Invasive Gynecology*, *30*(11), S100-S101. (N=58)

The retrospective data sets demonstrate feasibility of the use of the subject device for the expanded indications for use. The prospective dataset of 64 patients demonstrated no device-related failures. Procedure-related complications associated with retroperitoneal access for sentinel lymph node dissection included two conversions from retroperitoneal access to a traditional approach (3.1%, 2/64) and three cystotomies creating access for device placement (4.7%, 3/64). Complication rates for bleeding, infection, and injury to vessels or nerves were similar to those observed with traditional alternative approaches. The benefit of this device is providing access to the sentinel pelvic lymph node without requiring an abdominal incision, observed in 62/64 patients (96.9%).

Conclusion

Based on the intended use, technological characteristics, and performance testing results, the subject GelPOINT V-Path Transvaginal Access Platform with Retroperitoneal Access Device is considered substantially equivalent to the predicate device.