September 16, 2022

Applied Medical Resources Corporation
David Yu
Regulatory Affairs Specialist
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K220969
Trade/Device Name: GelPOINT® V-Path Vaginal Access System
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: MOK
Dated: August 17, 2022
Received: August 18, 2022

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 (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 and Part 809); 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

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)*
K220969

Device Name
GelPOINT® V-Path Vaginal Access System

Indications for Use *(Describe)*
The GelPOINT V-Path Vaginal Access System (VAS) is intended to be inserted in the vagina to allow for entry of minimally invasive instruments while maintaining insufflation for vaginal gynecological 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.

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510(k) Summary

GelPoint V-Path Vaginal Access System

K220969

510(K) Submitter:	Applied Medical Resources Corp. 22872 Avenida Empresa Rancho Santa Margarita, CA, 92688 (949) 713-8000
Contact Person:	David Yu Regulatory Affairs Specialist Applied Medical Resources Corp. David.Yu@appliedmedical.com Tel: (949) 713-8023 Fax: (949) 713-8205
Date of Preparation:	September 15, 2022
Trade Name:	GelPOINT® V-Path Vaginal Access System
Common Name:	Vaginal endoscopic surgery access port
Classification:	Regulation: 884.1630 Colposcope Device Class: Class II Product Code: MOK, Vaginoscope and accessories
Predicate Device:	Trade Name: KARL STORZ INFANT, BALLOON VAGINOSCOPE 510(k) #: K950639 Product Code: MOK Through FDA database search following predicate device has been identified: KARL STORZ INFANT BALLOON VAGINOSCOPE manufactured by KARL STORZ ENDOSCOPY-AMERICA, INC (K950639). **No design-related recalls for these legally marketed predicate devices have been identified.**
Indications for use:	The GelPOINT V-Path Vaginal Access System is intended to be inserted in the vagina to allow for entry of minimally invasive instruments while maintaining insufflation for vaginal gynecological procedures.

Device Description

The GelPOINT V-Path Vaginal Access System consists of an Intravaginal Alexis retractor and two access channels that are placed vaginally to create a pathway to gynecological organs. 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 5mm to 12mm instrumentation. Visualization is achieved via introduction of an endoscope through a sleeve. The device is provided sterile.

Comparison of Technological Characteristics with the Predicate Device

Manufacturer	**Applied Medical Resources Corp**	**KARL STORZ ENDOSCOPY-AMERICA, INC**
Trade Name	**GelPOINT V-Path Vaginal Access System** **K220969**	**KARL STORZ INFANT BALLOON VAGINOSCOPE** **K950639**
General Device Characteristics		
Device Design	The Vaginal Access System consists of similarly designed intravaginal Alexis retractor and a vaginal access channel that acts as the anchor for the intravaginal Alexis retractor. Intended 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	The device consists of a vaginoscopes, balloon vaginoscopes, vaginoscope sheaths, fiber optic light carrier and adjustable magnifiers. Designed to be used for endoscopic diagnostic and surgical procedures involving the infant vagina and cervix.
Anatomical Sites	Vagina	Vagina
Placement	Transvaginal	Transvaginal

Visualization Capability	Visualization is achieved via introduction of an endoscope through an access port.	N/A
Expansion of Surgical Space	Utilizes CO2 insufflation via an insufflator (not included with device) connected to insufflation port on the device.	N/A
Device Removals	The intravaginal Alexis retractor does not include a tether because the retractor is only placed at the vaginal introitus and can be removed after unrolling the outer ring. The access channel is also placed at the introitus and is removed manually by the user.	N/A
Materials	Polyether polyurethane, thermoplastic elastomer	N/A
Sterilization	Ethylene Oxide, Sterility Assurance Level of 10^{-6} Single use device; device is discarded after use	N/A

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

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

The differences in device design, presence of imaging capability, and material do not constitute a new intended use. Additionally, there are no different questions of safety and effectiveness that arise from the differences in technology. The technological differences between GelPOINT V-Path Vaginal Access System and the predicate device can be evaluated through performance testing and do not alter the intended use of the GelPOINT V-Path Vaginal Access System.

Discussion of Performance Data

The subject device and predicate device share the same ability to achieve vaginal access to the vaginal canal. Therefore, bench testing for the subject device was conducted to demonstrate the clinically relevant functionality to provide access to the vaginal canal.

There are no existing performance standards to evaluate the functions of the GelPOINT V-Path Vaginal Access System. A protocol was developed by Applied Medical to evaluate the ability of the subject device to provide access to the vaginal canal and remain anchored following deployment. Maintenance of insufflation and device removal were also assessed.

Function Testing

Functional bench testing was performed to demonstrate the adequate functionality of the Vaginal Access System, as follows:

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

The studies confirm that the GelPOINT V-Path Vaginal Access System 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 studies also confirm 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.

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 Vaginal Access System 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 Vaginal Access System 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

Clinical data are not needed to support substantial equivalence for the subject device.

Conclusion

The GelPOINT V-Path Vaginal Access System has the same intended use as the predicate device. The GelPOINT V-Path Vaginal Access System has different technological characteristics from the predicate device, but these differences do not raise different questions of safety and effectiveness. Performance testing, as described above, demonstrates that the GelPOINT V-Path Vaginal Access System is as safe and effective as the predicate. Therefore, the GelPOINT V-Path Vaginal Access System is substantially equivalent to the predicate device.