DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 20, 2017

Applied Medical Resources Corp.
Corinne Weisheit, Ph.D.
Regulatory Affairs Specialist I
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K171701
Trade/Device Name: GelPOINT® Path Transanal Access Platform
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FER
Dated: June 6, 2017
Received: June 8, 2017

Dear Corinne Weisheit:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171701

Device Name
GelPOINT® Path Transanal Access Platform

Indications for Use *(Describe)*
The GelPOINT Path Transanal Access Platform is indicated for multiple instrument or camera access through the anus to perform various diagnostic and/or therapeutic procedures by using additional instruments.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(K) Submitter: Applied Medical Resources Corp.
22872 Avenida Empresa
Rancho Santa Margarita, CA, 92688
(949) 713-8000

Contact Person: Corinne Weisheit, PhD
Regulatory Affairs Specialist I
Applied Medical Resources Corp.
cweisheit@appliedmedical.com
Tel: (949) 713-8176
Fax: (949) 713-8205

Date of Preparation: June 6, 2017

Trade Name: GelPOINT® Path Transanal Access Platform

Common Name: Transanal endoscopic surgery access port

Classification: Regulation: 21 CFR 876.1500, Endoscope & Accessories
Device Class: Class II
Product Code: FER

Predicate Device: Applied Medical's GelPOINT® Path Transanal Access Platform
510(k)#: K133393 and K110792
Product Code: FER

Device Description: GelPOINT Path is inserted into the anal canal to establish access to the rectum and lower sigmoid colon in preparation for transanal endoscopic surgery. The access channel lumen may be closed off with an airtight cap. The cap allows for insufflation of the surgical site. The cap is constructed of a gel material through which multiple sleeves may be placed. These sleeves establish ports that allow passage of a laparoscope and laparoscopic instruments without loss of insufflation.

GelPOINT Path was previously cleared in access channel lengths ranging from 4.5cm to 15cm. The proposed clearance for the access channel length is 3.5cm to 15cm.

Indications for use:

The GelPOINT Path Transanal Access Platform is indicated for multiple instrument or camera access through the anus to perform various diagnostic and/or therapeutic procedures by using additional instruments.

Comparison of Technological Characteristics with the Predicate Device

The subject device is a line extension to the GelPOINT Path Transanal Access Platform device family cleared in K110792 and K133393. Similarities to the predicate GelPOINT Path devices include:

- All dilate the anus to allow access to the surgical site.
- All are inserted using an introducer
- All are affixed to the patient via sutures
- All allow insertion of instruments including endoscopes
- All are made of polymers
- All are disposable
- All are capable of insufflation
- All have a detachable airtight cap that facilitates insufflation and removal of specimens

The predicate devices were cleared for access channel lengths ranging from 4.5cm to 15cm. The proposed device access channel will measure as short as 3.5cm. The shorter access channel better accommodates patients with shorter anal canals.

Discussion of Performance Testing

Safety and effectiveness for GelPOINT Path Transanal Access Platform was established in K110792 and K133393. Performance testing described in K110792 applies to the proposed clearance due to the fact that the access channel length does not impact the performance specifications required for the device's intended use.

Conclusion

The GelPOINT Path Transanal Access Platform with an access channel that is 3.5cm in length is substantially equivalent to the previously cleared range described in K110792 and K133393.