April 29, 2020

Applied Medical Resources Corp.
Mr. Frans Vandenbroek
Principal Regulatory Affairs Specialist
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K191866
Trade/Device Name: GelPOINT Mini Advanced Access Platform
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 27, 2020
Received: March 31, 2020

Dear Mr. Vandenbroek:

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); 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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191866

Device Name
GelPOINT Mini Advanced Access Platform

Indications for Use *(Describe)*
The GelPOINT Mini Advanced Access Platform is indicated for use in general, abdominal, gynecological, and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes, extraperitoneal spaces and/or potential spaces for endoscopic 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.

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K191866, 510(K) Summary

510(K) Submitter: Applied Medical Resources Corporation
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Date of Preparation: April 28, 2020

Trade Name: GelPOINT Mini Advanced Access Platform

Common Name: Endoscopic Access Device

Classification: 21CFR876.1500, Endoscope and Accessories.

Product Code: GCJ, Laparoscope, General and Plastic Surgery

Predicate Device: K060629, Applied Medical GelPort Blunt Tip Trocar System

Device Description: The proposed device is an iteration of Applied Medical's GelPort Blunt Tip Trocar System. The predicate GelPort system provides a single access port and must therefore be used in combination with additional ports. Three ports is common, each requiring a dedicated incision. The proposed device, in essence, combines three of the single port predicates into one compact construct that requires but a single incision. A fourth port is included in the package as an option.

The proposed device is a sterile, single-use instrument intended to access abdominal, thoracic and pelvic cavities in preparation for endoscopic surgical procedures. It features a sleeve type wound retractor and a detachable cap. The wound retractor consists of a flexible polyurethane cylindrical sheath that has a semi-rigid polyurethane inner ring attached at each end. The detachable Gel-cap is constructed of a semi-rigid polycarbonate ring and a flexible gel-like material. The Gel-cap is fastened to the wound retractor with a locking attachment lever.

	The Gel-cap can accommodate up to four access ports that are inserted through the gel in a formation preferred by the user. The ports accommodate laparoscopic tools ranging from 4.8 to 13.2mm and have sealing features that allow insufflation of the surgical space.
Intended Use:	The GelPOINT Mini Advanced Access Platform is indicated for use in general, abdominal, gynecological, and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes, extraperitoneal spaces and/or potential spaces for endoscopic instruments.

Summary of Technological Characteristics:

The predicate and proposed device share these technological characteristics:

- Both establish access ports for laparoscopic procedures executed in parts of the body ranging from the thorax to the pelvis.
- Both are inserted through incisions ranging from 1.5 – 4cm based on user preference.
- Both accommodate laparoscopic instruments ranging from 4.8 to 13.2mm.
- Both allow insufflation of the surgical space.
- Both have mechanisms for anchoring the device to the patient.

Compared to the predicate, the proposed device has these technological updates:

- Up to four endoscopic access ports delivered in a compact construct that is placed through a single incision.
- The lower portion of the device serves as a wound protector/retractor.
- The upper portion accommodates up to four access ports in a cap made of a flexible gel-type material. The quantity and location of the ports is based on user preference.
- The Gel-cap is exceptionally flexible which allows superior articulation of instruments placed through the ports.
- The Gel-cap closes the wound opening to allow insufflation of surgical spaces.
- The Gel-cap is detachable to accommodate removal of specimen.

Technological Similarities, Predicate and Proposed Device

	GelPort Blunt Tip Trocar System (Predicate)	**GelPOINT Mini Advanced Access Platform (Proposed Device)**
Intended use	Create an access channel for placing endoscopic instruments into body cavities under insufflated conditions	Same

	GelPort Blunt Tip Trocar System (Predicate)	**GelPOINT Mini Advanced Access Platform (Proposed Device)**
Indications for use	For use in general, abdominal, gynecological, and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes, extraperitoneal spaces and/or potential spaces for endoscopic instruments	Same
Anatomy	Area ranging from the pelvis to the thorax including the breast.	Same
Insertion	Through an incision based on surgeons experience with 12mm ports.	Through an incision ranging from 15 to 40mm.
Port requirement	The device delivers a single port. Since most endoscopic procedures require multiple ports, additional ports (and incisions) are required	The device provides three access ports in a single construct and requires but a single incision. A 4^{th} port is included as an option.
Port size	Single port, 12mm	Three 10mm, one 12mm port
Anchoring	Device is secured to the patient via a sliding bolster and an inflatable balloon. Loops for adding sutures (if desired) are provided	Device is secured to the patient via a sleeve type wound protector/retractor
Insufflation	Allows insufflation	Same
Visualization	Standard endoscope placed through access port	Same
Instrument capability	Endoscopic instruments ranging from 4.8 to 13.2mm	Same
Instruments articulation	Articulation and positioning of instruments is limited by rigidity of patient tissue	Articulation and positioning of instruments is superior due to flexibility of gel cap
Specimen removal	Limited. Oversize specimen requires removal of port	Superior. Detaching the gel cap provides a larger opening through a protected wound
Materials	Various polymers	Polymers and stainless steel
Sterility	E-beam irradiation, 25-60kGy	Gamma Irradiation, 27.5-40kGy

Discussion of Non-clinical Performance Testing:

Biocompatibility

A biocompatibility evaluation of the GelPOINT Mini Advanced Access Platform was conducted in accordance with the FDA's guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The proposed device contacts tissue for less than 24 hours and was found compatible after being subjected to these tests:

- Cytotoxicity
- Intracutaneous reactivity
- Sensitization

Functional Performance:

Side-by-side bench testing was performed on the proposed and predicate devices to demonstrate substantial equivalence. The tests focused on the functional performance of an endoscopic access device. Proposed and predicate devices were evaluated for:

- Resistance to detachment from the patient while operated as intended.
- System leak test with and without instruments.
- Seal particulation during instrument exchanges.
- The ability of the sealing system to reseal after removal instruments.
- The drag force created by inserting and removing instruments.

Results and Conclusions

Predicate and proposed devices met all testing acceptance criteria. Test results demonstrate substantial equivalence between the predicate and proposed device.