September 6, 2019

Applied Medical Resources Corp.
Corinne Yestrepsky
Regulatory Affairs Specialist II
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K191294
Trade/Device Name: Transvaginal Access Platform
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope And Accessories
Regulatory Class: II
Product Code: HEW
Dated: August 2, 2019
Received: August 7, 2019

Dear Corinne Yestrepsky:

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,

for Sharon M. Andrews
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191294

Device Name
Transvaginal Access Platform

Indications for Use *(Describe)*
The Transvaginal Access Platform is intended to be inserted transvaginally to establish a path of entry for minimally invasive instruments while maintaining insufflation during laparoscopic-assisted and vaginal gynecological procedures. 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.

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510(k) Summary – K191294

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

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

Date of Preparation: September 6, 2019

Trade Name: Transvaginal Access Platform

Common Name: Transvaginal endoscopic surgery access port

Classification: Regulation: 21 CFR 884.1640, Culdoscope & Accessories
Device Class: Class II
Product Code: HEW (culdoscope and accessories)

Predicate Device: Trade Name: GelPOINT Transvaginal Access Platform
510(k) #: K143308
Product Code: HEW
The predicate device has not been subject to a design related recall.

Device Description: The Transvaginal Access Platform consists of an access channel component that is placed transvaginally to create a pathway to gynecological organs in the pelvic cavity. A GelSeal cap attaches to the access channel 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 Transvaginal Access Platform is intended to be inserted transvaginally to establish a path of entry for minimally invasive instruments while maintaining insufflation during laparoscopic-assisted and vaginal gynecological procedures. The device is also a conduit for the extraction of specimens.

Comparison with the Predicate Device

The subject and predicate device have different indications for use statements. The predicate device is indicated only for laparoscopic hysterectomy, while the subject device is indicated for laparoscopic assisted and vaginal gynecologic procedures. The key difference is that the subject device can be used during a procedure that only relies on vaginal access (i.e., no laparoscopic access), as well as laparoscopic-assisted gynecologic procedures other than hysterectomy. In addition, the subject device indication uses the term "maintaining insufflation" versus the "maintaining pneumoperitoneum" term used in the predicate device indication. This change in terminology is to account for insufflation of the vaginal canal when the subject device is in use.

The subject and predicate device have the same intended use – establishing a path of entry for instruments, maintaining insufflation, and serving as a conduit for extraction of specimens during minimally invasive gynecologic procedures.

The subject and predicate device have different technological characteristics, including device retention, instrument compatibility, specimen removal method and size, device removal, and device materials. These differences in technological characteristics do not raise different questions of safety or effectiveness.

Discussion of Performance Data

The following performance testing was provided to support a substantial equivalence determination:

- Sterilization validation
- Shelf life testing including transportation simulation, package integrity, and device functionality testing
- Biocompatibility including cytotoxicity per ISO 10993-5 and irritation and sensitization testing per ISO 10993-10
- Mechanical performance testing including assessments of the following:
    - Maintenance of transvaginal access
    - Facilitation of instrument access to surgical site
    - Device removal
    - Device retention
    - Maintenance of insufflation
- Clinical performance data
    - Baekelandt et al (2018) – randomized, single-center, single-blinded trial to compare hysterectomy by Transvaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) versus total laparoscopic hysterectomy (TLH) (n=70)
    - International Natural Orifice Transluminal Endoscopic Surgery (iNOTESs) Society Registry data (n=906)
    - Both data sets demonstrated acceptable rates of peri- and post-operative

complications following use of the subject device.

Conclusion

Based on the intended use, technological characteristics, and performance testing results, the subject Transvaginal Access Platform device is considered substantially equivalent to the predicate device.