DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 13, 2015

Applied Medical Resources
Frans VandenBroek
Principal Regulatory Affairs Specialist
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K143308
Trade/Device Name: GelPOINT Transvaginal Access Platform, Models: C2A00, C2A01, C2A02
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: II
Product Code: HEW
Dated: September 10, 2015
Received: September 29, 2015

Dear Frans 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. 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 yours,

Benjamin R. Fisher -S

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)*
K143308

Device Name
GelPOINT Transvaginal Access Platform, Models: C2A00, C2A01, C2A02.

Indications for Use *(Describe)*

The GelPOINT Transvaginal Access Platform is intended to be inserted transvaginally to establish a path of entry for minimally invasive instruments while maintaining pneumoperitoneum during laparoscopic hysterectomy. The instrument is indicated for use in laparoscopic assisted vaginal hysterectomies. The instrument 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

I. SUBMITTER

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Contact Person**:** Frans VandenBroek
Date Prepared: Oct 12, 2015

II. DEVICE

Name: GelPOINT Transvaginal Access Platform, Models: C2A00, C2A01, C2A02
Common name: Transvaginal Access Device
Classification Name: Culdoscope and Accessories, (21CFR 884.1640)
Regulatory Class: II
Product code: HEW.

III. PREDICATE DEVICE

McCartney Access Tube, Gynetech Pty. LTD (K051594)

Reference Device: Applied Medical GelPOINT Path Transanal Surgery Device (K133393)

IV. DEVICE DESCRIPTION

The GelPOINT Transvaginal Access Platform is a sterile, single use instrument that allows access to the vagina to perform laparoscopic assisted hysterectomy. The device consists of a cannula with suture ties, and a cap made of a flexible gel-like material. The gel cap has two stopcocks that can be used for insufflation or smoke evacuation. Four trocars are included and may be placed through the gel cap. The trocars allow insertion of standard laparoscopic instruments into the vagina. Construction materials include various polymers, silicone and stainless steel.

Packaging consists of a PTEG tray that is placed in a Tyvek/Mylar pouch and shipped in a carton. Sterilization is via Gamma irradiation; sterility assurance level is 10^{-6}.

V. INDICATIONS FOR USE

The GelPOINT Transvaginal Access Platform is intended to be inserted transvaginally to establish a path of entry for minimally invasive instruments while maintaining pneumoperitoneum during laparoscopic hysterectomy. The instrument is indicated for use in laparoscopic assisted vaginal hysterectomies. The instrument is also a conduit for the extraction of specimens.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

GelPOINT and predicate device have different technological characteristics as follows:

- GelPOINT is delivered in three diameters and lengths; predicate is delivered in two diameters.
- GelPOINT is shorter.
- GelPOINT has (up to) four access ports. The predicate has three.
- GelPOINT uses an introducer to facilitate insertion.
- GelPOINT uses sutures for fixation to the patient. The predicate connects to the surgical drapes using towel clips.

VII. PERFORMANCE DATA

The following performance data support determination of substantial equivalence.

Biocompatibility testing

The subject device is an External Communicating Device that contacts Tissue/Bone/Dentin for less than 24 hours. The portion of the device that contacts tissue is the cannula, dilator and the cap ring. Biocompatibility testing on the reference device (K133393), which is identical in materials and composition to the subject device, were leveraged to support the biocompatibility of the subject device. All patient-contacting device components have passed biocompatibility testing required by ISO 10993-1 and FDA General Program Memorandum G95-1. These tests include:

- Cytotoxicity
- Sensitization
- Irritation

Mechanical testing

There are no published performance standards for devices of this type. Therefore, Applied Medical created a dedicated test method designed to confirm substantial equivalence to the Gynetech McCartney Access Tube. These tests focused on:

- Sealing against insufflation pressure, with and without instruments in place
- Fixation in the vagina

VIII. CONCLUSIONS

The Applied Medical GelPOINT Transvaginal Access Platform is substantially equivalent to the predicate Gynetech McCartney Access Tube.