K110792

Applied Medical

510(k) SUMMARY

MAY 2 3 2011

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA, 92688
(949) 713-8000

CONTACT PERSON: Frans VandenBroek
Principal Specialist, Regulatory Affairs
(949) 713-8369
(949) 713-8205 (FAX)

DATE OF PREPARATION: April 25, 2011

TRADE NAME: GelPOINT Path Transanal Access Platform

COMMON NAME: Transanal surgical access device

CLASSIFICATION NAME: Endoscope and Accessories, Gastroenterology and Urology Devices, 21CFR 876.1500, product code FER.

PREDICATE DEVICE: Covidien SILS™ Port. K103253

DEVICE DESCRIPTION: The GelPOINT Path is a sterile, single use, disposable surgical instrument designed to provide multiple instrument or camera access into the rectal cavity and lower sigmoid colon. The device is used in concert with standard laparoscopic instruments and is substantially equivalent to the predicate device in intended use, concept, function and performance.

INTENDED USE: The GelPOINT Path is indicated for multiple instrument or camera access through the anus for rectal procedures such as TEMS (Transanal Endoscopic Micro Surgery), flap revision and fistula repair.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
The GelPOINT Path is technologically similar to the predicate device in that both designs:

- Have insufflation capability
- Have 3 ports that can seal against insufflation pressure as instruments are inserted
- Can accommodate standard laparoscopes and laparoscopic instruments
- Have a flexible construction that allows articulation of instrumentation
- Are made of various polymers
- May be sutured to the patient to assist retention
- Have smoke evacuation capability

The GelPOINT Path is technologically different from the predicate device in that:

- Instrumentation placed through GelPOINT Path may be articulated over a greater range of motion because the device's flexible component is outside the anus. The predicate device's flexible component is inside the rectum.
- GelPOINT Path uses an introducer to facilitate insertion; the predicate device is compressed during insertion.
- GelPOINT Path's three trocars can accommodate instruments ranging from 5 to 10mm. The predicate's three trocars can accommodate three 5mm instruments or two 5mm and one 12mm instruments.
- GelPOINT Path's cap may be detached from the access channel. This allows removal of specimens that are too large to be removed through the three trocars.
- GelPOINT Path is sterilized via radiation; the predicate is sterilized via Ethylene Oxide.

DISCUSSION OF NONCLINICAL TESTS SUBMITTED:

Applied Medical created a dedicated test method to confirm substantial equivalence of the GelPOINT Path device to the Covidien SILS Port predicate. These tests focused on:

- Maximum insufflation flow rate capability
- Sealing capability to allow and maintain insufflation
- Establishing retention in the rectum

CONCLUSIONS DRAWN FROM TESTING:

The Applied Medical GelPOINT Path device is substantially equivalent in performance to the Covidien SILS Port device in:

- Establishing rapid insufflation
- Maintaining insufflation pressures as normal leakage occurs throughout the procedure
- Retention in the rectum

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Applied Medical Resources Corp.
c/o Mr. Jeffrey D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
RESEARCH TRIANGLE NC 27709

MAY 2 3 2011

Re: K110792
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: May 4, 2011
Received: May 12, 2011

Dear Mr. Rongero:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not yet assigned K110792

Device Name: GelPOINT Path Transanal Access Platform

Indications for Use: The GelPOINT Path is indicated for multiple instrument or camera access through the anus for rectal procedures such as TEMS (Transanal Endoscopic Micro Surgery), flap revision, and fistula repair.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110792