Applied Medical

JAN - 2 2014

510(k) SUMMARY

510(k) OWNER: Applied Medical Resources Corporation
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(949) 713-8000

CONTACT PERSON: Frans VandenBroek
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(949) 713-8369
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DATE OF PREPARATION: November 1, 2013

TRADE NAME: GelPOINT Path Transanal Access Platform

COMMON NAME: Transanal Endoscopic Microsurgery (TEM) device

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

PREDICATE DEVICE: K070915, SAPIMED S.P.A. Disposable Sigmoidoscope/ proctoscope; product code KOG, Endoscope and accessories.

K110792, Applied Medical Resources GelPOINT Path Transanal Access Platform; product code FER, Anoscope and accessories.

DEVICE DESCRIPTION: The subject device is inserted into the rectum to establish an access port into the lower sigmoid colon in preparation for transanal endoscopic microsurgery. The port lumen measures 40mm in diameter and may be capped off with an airtight lid. The lid allows the colon to be insufflated, thus enlarging the operative space.

The airtight lid is constructed of a gel material through which multiple trocars may be placed. These trocars establish multiple ports that allow passage of laparoscopes and laparoscopic instruments without loss of insufflation. The design has all the functionality of a simple, two-piece proctoscope but with significant additional versatility, capability and effectiveness.

INTENDED USE: The subject device was previously cleared in K110792 and its intended use is unchanged. It provides access to the rectal cavity to perform surgery, which is also the intended use of the Sapimed disposable proctoscope, cleared in K070915. The subject device has all the functionality of the Sapimed proctoscope with the additional benefit of

delivering greater access and operative space. Therefore, the indications for the Sapimed device may be incorporated into the indications for the subject device as follows:

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

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The design of the subject device is unchanged since it was cleared in K110792. Similarities to the predicate Sapimed proctoscope are:

- Both dilate the anus to allow access to the rectal cavity
- Both are inserted using a dilator
- Both allow insertion of instruments including endoscopes
- Both are made of polymers
- Both are disposable
- Both are capable of insufflation

The predicate Sapimed proctoscope consists of two simple injection molded components, a 17mm cannula and an insertion dilator. By comparison, the subject device is more versatile. Differences include:

- The cannula is larger in diameter (40mm vs. 17mm) and shorter (4.5cm vs 14cm)
- Insufflates with a CO2 pump. The predicate device insufflates with a hand held bulb
- May be sutured to the patient to assist retention
- Allows instrumentation to be articulated over a greater range of motion
- Has three access ports, each of which can accommodate standard laparoscopic instruments 10mm and smaller
- A detachable airtight cap allows removing specimens that are too large to be removed through the proctoscope's lumen

Safety and efficacy of the subject device and the Sapimed proctoscope were previously established in K110792 and K070915. In spite of the differences in design, the subject device functions—in essence—as a proctoscope with greater insufflation capability. Insufflation enlarges the operative field and therefore more effectively allows execution of medical procedures in the colon.

DISCUSSION OF NONCLINICAL TESTS SUBMITTED: Subject and predicate device were both previously cleared for accessing the rectum. However, the subject device has numerous superior technological capabilities, not available in the Sapimed proctoscope. There are no recognized standard tests that can challenge and compare these technological differences. Therefore, substantial equivalence was established based on a dimensional analysis of each device.

CONCLUSIONS DRAWN FROM TESTING: The subject device is substantially equivalent in performance to the Sapimed proctoscope but has numerous technological advantages that increase effectiveness. Therefore, the indications for use of the subject device may be updated by incorporating the indications of the Sapimed device.

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

January 2, 2014

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

Re: K133393
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: November 1, 2013
Received: November 5, 2013

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 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,

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

INDICATIONS FOR USE

510(k) Number (if known): K133393

Device Name: GelPOINT Path Transanal Access Platform

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 therapeutic procedures by using additional accessories.

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)

Benjamin R. Fisher -S
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