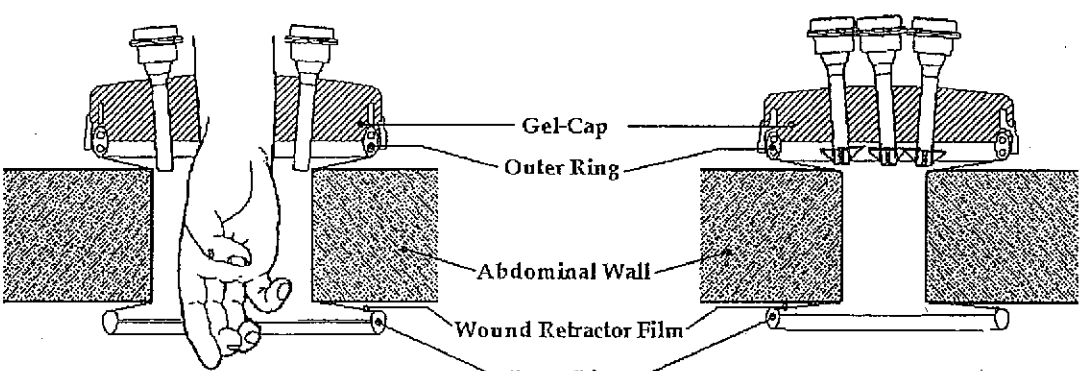
K090275

FEB 18 2009

510(k) SUMMARY

SUBMITTED BY:	Applied Medical Resources Corporation 22872 Avenida Empresa Rancho Santa Margarita, CA-92688 (949) 713-8000 (949) 713-8205 (FAX)
CONTACT PERSON:	Frans VandenBroek Vice President, Regulatory Affairs fvandenbroek@appliedmedical.com
DATE OF PREPARATION:	January 8, 2009
TRADE NAME:	To be determined
COMMON NAME:	Single Incision Access System
CLASSIFICATION NAME:	Laparoscope, General & Plastic Surgery (21CFR 876.1500, product code GCJ)
PREDICATE DEVICE:	K014047, Applied GelPort Laparoscopic Hand Access Device

DEVICE DESCRIPTION: The subject device is a modified version of the predicate device. It has a simpler design, specific indications for use and allows a surgeon to choose an alternate method of accessing body cavities. It also improves patient safety by reducing the size of an abdominal incision.



PREDICATE DEVICE
K014047

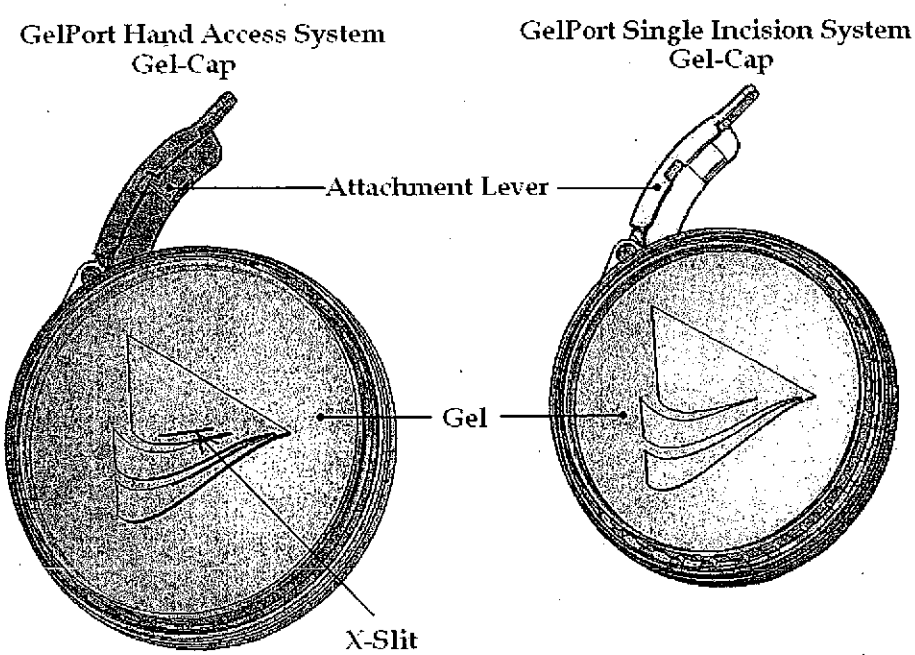
SUBJECT DEVICE

The predicate device of K014047 accommodates insertion of a hand during a Hand Assisted Laparascopic (HAL) procedure. It consists of a disk-like Gel-Cap that is positioned over an incision in the patient's abdomen. The Gel-Cap is constructed of a gel material and has a slit in the center. The slit is normally closed, thus allowing insufflation of the peritoneum. When a hand is placed through the slit, the gel material conforms and seals against the hand, thus preventing loss of peritoneal pressure. The Gel-Cap also accepts placement of trocars around the periphery.

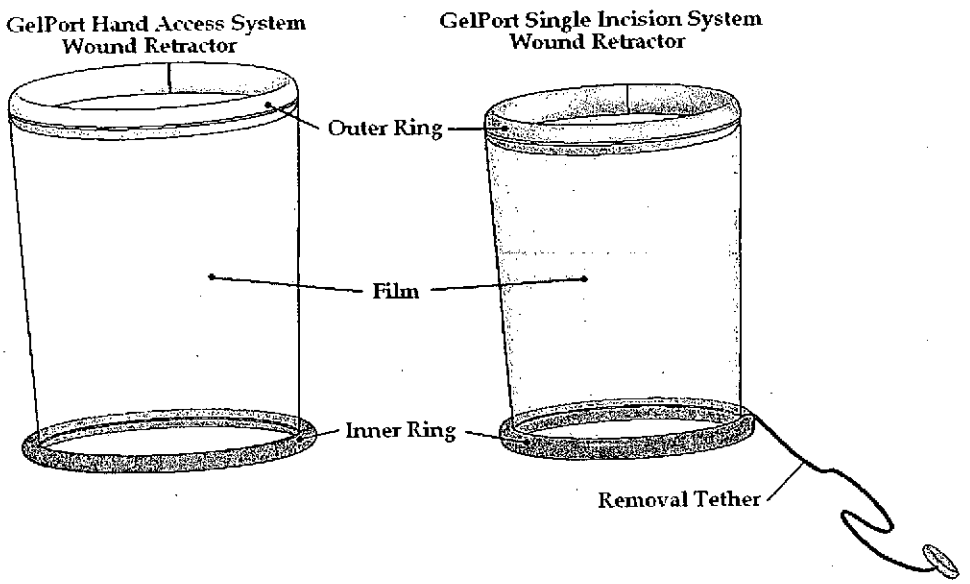
The subject device is designed for surgeons who prefer to perform laparascopic surgery without a hand in the peritoneum. There is no slit, thus simplifying the role of the Gel-Cap to a means of accommodating trocars only. The trocars are clustered near the center of the Gel-Cap which allows the abdominal incision to be smaller. The indications for use changes from "hand access plus trocars" to "trocars only". APPLIED refers to the resulting device as a Single Incision Access System. The new system will be available in diameters of 40-120mm for use in incisions ranging from 15-90mm.

INTENDED USE: For use in patients undergoing laparoscopic surgical procedures to obtain abdominal access by instrumentation. Trocars may be placed through the Gel Seal Cap to allow instrument access to the surgical site. The (device) may be used in procedures such as nephrectomy, colectomy and splenectomy in colorectal, urological and general surgery to access the surgical site.

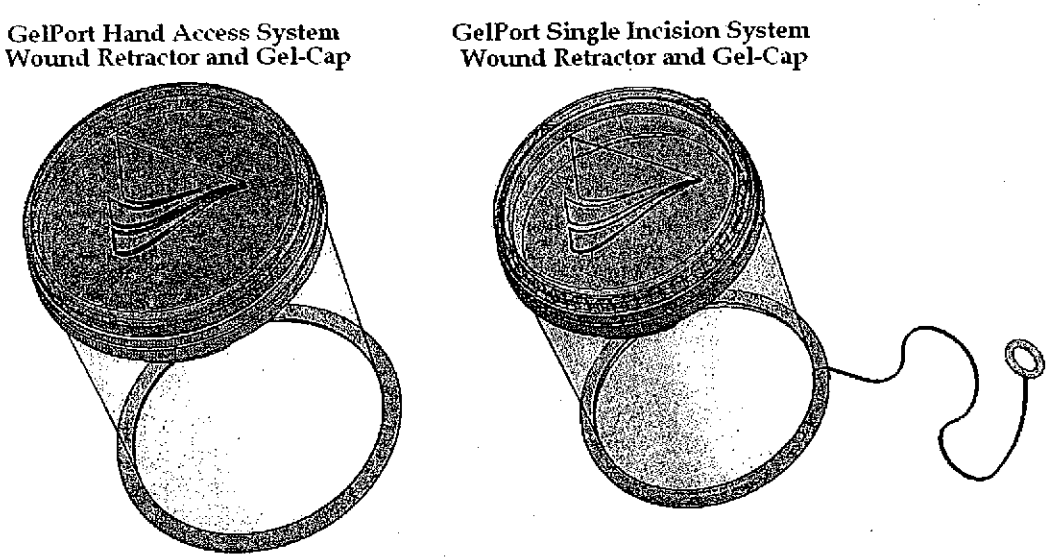
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The predicate and subject device consists of a Gel-Cap and wound retractor. The Gel-Cap is constructed of a semi-rigid polycarbonate ring and a flexible gel-like material. An attachment lever locks the cap onto the wound retractor.



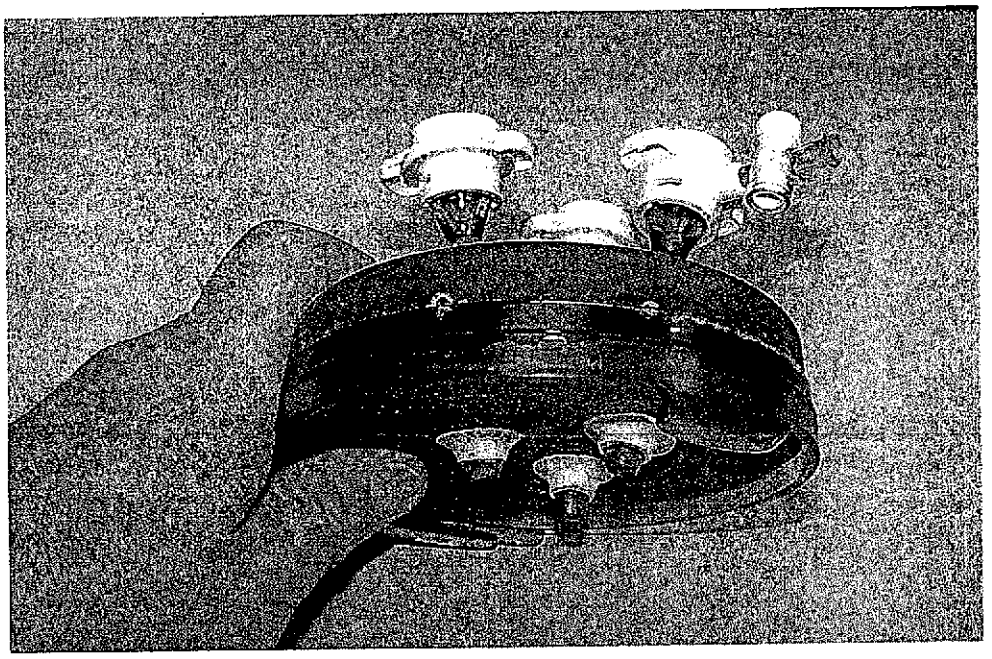
The wound retractor consists of a thin-film flexible cylinder that has semi-rigid polyurethane rings at each end. The inner ring - which is placed in the patient's abdominal cavity - has a tether that aids removal of the wound retractor at the end of the procedure.



The Gel-Cap attaches to the outer ring of the wound retractor via the attachment lever. The graphic below shows the assembled GelPort system. However, in an actual procedure, the Gel-Cap would be attached to the wound retractor only after the retractor has been placed in the patient's abdomen.



APPLIED plans to market the subject device individually and also in a convenience kit. The kit will include trocars from APPLIED's extensive trocar model family. Those trocars will have a flange at the distal end of the cannula to prevent the cannulas from migrating during instrument exchanges (See graphic, next page).



Bottom view of Gel-Cap with trocars inserted; white disks are retention flanges

DISCUSSION OF NONCLINICAL TESTS SUBMITTED: There are currently no recognized standards that specify performance characteristics of Single Incision Access Systems. Therefore, APPLIED set up testing to confirm safety and efficacy of the subject device relative to the predicate device of K014047. These tests include determination of:

- Minimum Incision Size – the minimum incision required to install the inner ring of the wound retractor.
- Leak Testing – the ability of the system to maintain pneumoperitoneum before and after multiple insertions of trocars through the Gel-Cap.
- Particulate Testing – the ability of the system to resist gel particulation caused by inserting trocars through the Gel-Cap.
- Leak testing after vigorous manipulation of trocars.

A discussion of the test method and results is in Section 15.

CONCLUSIONS DRAWN FROM TESTING: APPLIED's performance and functional testing demonstrated that the GelPort Single Incision Access System is substantially equivalent to the predicate device of K014047 and introduces no new safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Applied Medical Resources Corporation
% Underwriters Laboratories, Inc.
Mr. Morten S. Christensen
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San Jose, California 95131-1230

FEB 1 8 2009

Re: K090275
Trade/Device Name: GelPort Single Incision Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 2, 2009
Received: Febriaru 4, 2009

Dear Mr. Christensen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David Krone

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): ~~Not yet assigned~~. K090275

Device Name: GelPort Single Incision Access System.

Indications for Use:

For use in patients undergoing laparoscopic surgical procedures to obtain abdominal access by instrumentation. Trocars may be placed through the Gel Seal Cap to allow instrument access to the surgical site. The device may be used in procedures such as nephrectomy, colectomy and splenectomy in colorectal, urological and general surgery to access the surgical site.

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 General, Restorative, and Neurological Devices

510(k) Number K090275