K121336

SURGIQUEST, INC.
Modified SurgiQuest AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000 Special 510(k) Notification

XI. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

JUL 3 2012

SUBMITTER	SurgiQuest, Inc. 333 Quarry Road Milford, CT 06460
CONTACT PERSON	Daniel Donovan Sr. Director of Operations - SurgiQuest, Inc.
DATE PREPARED	February 24, 2012
CLASSIFICATION	Endoscope and accessories under 21 C.F.R. 876.1500; Laparoscopic Insufflator under 21 C.F.R. 884.1730 Product Code: GCJ and HIF Class: II
COMMON NAME	Disposable Endoscopic Trocar and Cannula; Carbon Dioxide Insufflator for Laparoscopy
PROPRIETARY NAME	SurgiQuest AirSeal® iFS (Name subject to change)
PREDICATE DEVICE(S)	SurgiQuest AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS2000 SurgiQuest, Inc. (Orange, CT) K103692
DEVICE DESCRIPTION	The SurgiQuest AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000 (the "DPIS 2000 System") consists of the following major components: (1) a trocar, (2) a cannula, (3) tube sets, and (4) a micro-processor controlled insufflation, recirculation and filtration unit (the "DPIS 2000 Unit"). The cannula, trocar and tube sets are sterile, single-use products. The DPIS 2000 Unit is non-sterile and reusable.
INDICATIONS FOR USE	The SurgiQuest AirSeal Optical Trocar & Cannula System with integrated Insufflator DPIS 2000 (the "DPIS 2000 System") is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the peritoneal cavity by filling it with gas, to establish and maintain a path of entry for endoscopic instruments, and to evacuate surgical smoke. The trocar of the DPIS 2000 System is indicated for use with or without visualization.
TESTING	The device has been tested to show its ability to create and maintain a port of entry during simulated laparoscopic surgery. It has also been tested to show its ability to maintain adequate pneumoperitoneum during the course of laparoscopic surgery and to aid in the evacuation of smoke. Sterility validation is in accordance with ISO 11137:2006

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Sterilization of Health Care Products -- Radiation -- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process For Medical Devices and AAMI TIR 27:2001, Sterilization of Healthcare Products – Radiation Sterilization – Substantiation of 25kGY as a Sterilization Dose - Method VD Max

A Sterility Assurance Level (SAL) of 10^{-6} is achieved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surgiquest, Incorporated
% Mr.Daniel Donovan
Senior Director of Operations
333 Quarry Road
Milford, Connecticut 06460

JUL 3 2012

Re: K121336
Trade/Device Name: Modified SurgiQuest AirSeal®Optical Trocar & Cannula System with Integrated Insufflator DPIS 2000
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: Class II
Product Code: HIF, GCJ
Dated: June 18, 2012
Received: June 22, 2012

Dear Mr. Donovan:

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,

Erin D Keith

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

Enclosure

Indications for Use

510(k) Number (if known): K121336

Device Name: Modified SurgiQuest AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000

Indications For Use:

The SurgiQuest AirSeal Optical Trocar & Cannula System with integrated Insufflator DPIS 2000 (the "DPIS 2000 System") is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the peritoneal cavity by filling it with gas, to establish and maintain a path of entry for endoscopic instruments, and to evacuate surgical smoke. The trocar of the DPIS 2000 System is indicated for use with or without visualization.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121336