K132169

XI. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER	SurgiQuest, Inc. 333 Quarry Road Milford, CT 06460
CONTACT PERSON	Daniel Donovan Sr. Director of Operations - SurgiQuest, Inc. Phone:203.799.2400 ext 202
DATE PREPARED	July 9, 2013
CLASSIFICATION	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 Modified SurgiQuest AirSeal® Optical Trocar & Cannula System with Integrated Insufflator DPIS 2000 SurgiQuest, Inc. (Milford, CT) K121336
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. The subject device of this filing is a modification to the original filing. The modification is to allow the operation of two trocars simultaneously, one AirSeal trocar and one conventional trocar. The predicate filing was a modification to allow the simultaneous operation of two AirSeal® trocars. The device has met the criteria for acceptance, safety and effectiveness and is substantially equivalent to the predicate.

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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 Engineering test summaries accompany this filing: 1. Engineering Test 0627131045_01, "iFS with Smoke Evac PLUS filtered tube set study" 2. Engineering Test 0627131059_01, "Smoke Evac PLUS filtered tube set Co2 Consumption Study" Sterility validation of reusable devices is in accordance with ISO 11137:2006 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 Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Daniel Donovan
Senior Director of Operations
SurgiQuest, Incorporated
333 Quarry Road
Milford, Connecticut 06460

Re: K132169
Trade/Device Name: 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: August 1, 2013
Received: August 6, 2013

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 contact 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. 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,

Mark N. Melkerson -S

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

Enclosure

IX. STATEMENT FOR INDICATIONS FOR USE

510(k) Number: K132169

Device Name: 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: Yes

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

Concurrence of CDRH, Office of Device Evaluation

Joshua C. Nipper -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132169