K103652

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

MAY 25 2011

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Submitter:	SurgiQuest, Inc. 12 Cascade Blvd. – Suite 2B Orange, CT 06477
Contact Person:	Daniel Donovan Sr. Dir., Operations Phone: (203) 799-2400 Ext. 202 Fax: (203) 799-2401 e-mail: ddonovan@surgiquest.com
Date Prepared:	December 10, 2010
Trade Name:	SurgiQuest AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000 (Trade name subject to change)
Common Name:	Disposable Endoscopic Trocar and Cannula; Carbon Dioxide Insufflator for Laparascopy
Classification Name:	Endoscope and accessories under 21 C.F.R. 876.1500; Laparoscopic Insufflator under 21 C.F.R. 884.1730
Regulatory Class:	II
Product Code:	GCJ and HIF
Predicate Devices:	SurgiQuest AirSeal Optical Trocar & Cannula System, SurgiQuest, Inc., k071571 AirSeal Optical Trocar & Cannula System, SurgiQuest, Inc., k083211 SurgiQuest AirSeal Optical Trocar & Cannula System SurgiQuest, Inc., k092504 45L High Core Insufflator F114 W.O.M. World of Medicine AG, k063367

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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 DPIS 2000 Unit is designed to function in one of three (3) separate modes of operation: (a) Insufflation Mode; (b) AirSeal Mode; or (c) Smoke Evacuation Mode.

Intended 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.

Substantial Equivalence:

The DPIS 2000 System is substantially equivalent to the AirSeal Predicate Device (k071571, k083211, k092504) and to the Insufflation Predicate Device (k063367). Specifically, the proposed device has the same intended use and the same indication for use as the Predicate Devices. In addition, the DPIS 2000 System and the Predicate Devices use the same or similar basic operating principles and incorporate the same or similar basic design features. Finally, biocompatibility, sterility, packaging and bench testing demonstrate the safety and effectiveness of the proposed device.

Bench test results demonstrate that the DPIS 2000 System is safe and effective in creating and maintaining pneumoperitoneum in all three modes.

The DPIS 2000 Unit has been developed in accordance with 21 CFR 820, ISO 13485:2003 & ISO 14971:2007

and will be tested in accordance with IEC 60601-1, General Requirements for Medical Electrical Equipment - Part 1: General Requirements for Safety and IEC60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

Gamma sterility validation has been performed (and will be in the case of the Smoke Evacuation Tube Set) in accordance with ISO 11137 Sterilization of health care products – Radiation, Part 1 – Part 3 and AAMI TIR 27, Sterilization of Healthcare Products: Radiation Sterilization - Substantiation of 25kGY as a Sterilization Dose - Method VD Max. ETO sterility validation has been performed ISO 11135-1, Sterilization of health care products –Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices; and ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals. Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 5 mg / 10 days and ECH < 5 mg / 10 days that remain on the tube set will not be exceeded.

A sterility assurance level (SAL) is $\leq 10^{-6}$ achieved. The foregoing sterility validation testing will be performed on the Smoke Evacuation Tube Set.

Package and product integrity were tested in accordance with ISO11607-1, Packaging for Terminally Sterilized Medical Devices and ASTM-F-1980-02, Standard for Accelerated Aging of Sterile Medical Device Packages. ISO 11137 -2, Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.

Finally, biocompatibility testing has been performed on the cannula, the optical trocar, the blunt tipped trocar including fixation device and the AirSeal® Tube Set (and will be in the case of the Smoke Evacuation Tube Set) in accordance with ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for InVitro Cytotoxicity; ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Type

Hypersensitivity,; and ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Material.]

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, Inc.
% Mr. Daniel Donovan
Sr. Director of Operations
12 Cascade Boulevard, Suite 2B
Orange, Connecticut 06477

MAY 25 2011

Re: K103692
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: May 18, 2011
Received: May 19, 2011

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,

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

Enclosure

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

INDICATIONS FOR USE STATMENT

510(k) Number (if known): K103692

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nichol Dyer for MXN
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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