K083211

DEC 15 2008

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER	SurgiQuest, Inc. 12 Cascade Blvd. – Suite 2B Orange, CT 06477
CONTACT PERSON	Kourosh Azarbarzin Founder & C.E.O. - SurgiQuest, Inc.
DATE PREPARED	May 25, 2007
CLASSIFICATION	Laparoscopic trocar, GCJ Class: II
COMMON NAME	Disposable Endoscopic Trocar & Cannula
PROPRIETARY NAME	SurgiQuest™ AirSeal™ Optical Trocar & Cannula System *(Trademark name to be determined)*
PREDICATE DEVICE(S)	Surgiport™ Blunt Tip Trocar U.S. Surgical Corp. (Norwalk, CT) K903419 EndoPath III Trocar System Ethicon Endo-Surgery, Inc. (Cincinnati, OH) K032676 Elastomeric Optical Trocar & Cannula SurgiQuest, Inc. (Orange, CT) K063859 LapEvac Filtration Device for the Pneumoperitoneum Buffalo Filter (Buffalo, NY) K052797 Sun Medical Smoke / Fluid Evacuation System Sun Medical Inc. (Arlington, TX) K911154
DEVICE DESCRIPTION	The subject is a surgical trocar and cannula composed of medical grade materials. The device is used to create and maintain a port of entry during endoscopic surgery and evacuate surgical smoke. It incorporates a gas seal utilizing CO_2, to maintain pneumoperitoneum during the course of surgery. It is supplied with a re-circulation and filtration pump

designed–to maintain pneumoperitoneum and minimize CO_2 consumption during minimally invasive surgery. The recirculation and filtration pump is reusable. The AirSeal™ Trocar & Cannula and Tube Set are fully disposable and are intended for single use only.

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.
(See Addendum 3 for test data regarding smoke evacuation)

The unit has been tested for safety and emissions in accordance with IEC60601-1, General Requirements for Safety 1: Collateral Standard: Safety Requirements for Medical Electrical Systems and IEC60601-1-2, General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

Sterility validation 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
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2008

Mr. Kourosh Azarbarzin
Founder & CEO
SurgiQuest, Incorporated
12 Cascade Boulevard, Suite 2B
ORANGE CT 06477

Re: K083211
Trade/Device Name: SurgiQuest™ AirSeal™ Optical Trocar and Cannula System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 1, 2008
Received: October 31, 2008

Dear Mr. Azarbarzin:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SurgiQuest, Inc.
AirSeal™ Optical Trocar & Cannula System
Special 510(k) Notification

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: K083211

Device Name: SurgiQuest™ AirSeal™ Optical Trocar & Cannula System *(Trademark name to be determined)*

Indications for Use: The SurgiQuest AirSeal™ Optical Trocar & Cannula System has applications in abdominal and thoracic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments and to evacuate smoke. The trocar may be used with or without visualization for primary and secondary insertions.
(Note: This Indication has been expanded to include smoke evacuation)

Prescription Use: Yes

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

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083211