

K071571

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

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER SurgiQuest, Inc.
12 Cascade Blvd. – Suite 2B
Orange, CT 06477 JUL 30 2007

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. It incorporates a gas seal utilizing CO₂, to maintain pneumoperitoneum during the course of surgery. It is supplied with a re-circulation and filtration pump designed to maintain pneumoperitoneum and minimize CO₂ consumption during

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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 simulated laparoscopic surgery.

The unit will be 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SurgiQuest, Inc.
% Mr. Kourosch Azarbarzin
Founder & CEO
12 Cascade Blvd., Suite 2B
Orange, CT 06477

JUL 30 2007

Re: K071571

Trade/Device Name: SurgiQuest™ AirSeal™ Optical
Trocar & Cannula System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 6, 2007
Received: June 8, 2007

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.

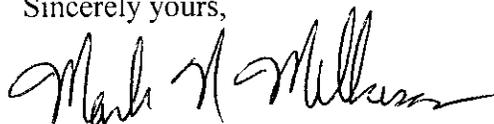
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Kourosh Azarbarzin

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 (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



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

Enclosure

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: _____

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. The trocar may be used with or without visualization for primary and secondary insertions.



(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

Prescription Use: Yes

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

Concurrence of CDRH, Office of Device Evaluation