SURGIQUEST, INC.
510(K) NOTIFICATION
SurgiQuest AnchorPort® Optical Trocar & Cannula SIL Kit

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

MAY - 5 2010

SUBMITTER	SurgiQuest, Inc. 12 Cascade Boulevard, Suite 2B Orange, CT 06477 Phone: 203.799.2400
CONTACT PERSON	Kourosh Azarbarzin Founder & C.E.O. - SurgiQuest, Inc.
DATE PREPARED	January 8, 2010
CLASSIFICATION	Laparoscopic trocar, GCJ Class: II
COMMON NAME	Disposable Endoscopic Optical Trocar & Cannula Kit
PROPRIETARY NAME	SurgiQuest AnchorPort® SIL Kit
PREDICATE DEVICE	SurgiQuest Elastomeric Optical trocar & Cannula SurgiQuest, Inc. (Orange, CT) K 063859 GelPOINT System Applied Medical (Rancho Santa Margarita, CA) k090275 SILS™ Port Covidien LP (North Haven, CT) K082619 Surgiport™ Blunt Tip Trocar U.S. Surgical Corp. (Norwalk, CT) K903419 EndoPath III™ Trocar System Ethicon Endo-Surgery, Inc. (Cincinnati, OH) K032676
DEVICE DESCRIPTION	The subject is a surgical trocar and cannula kit is composed of biosafe materials. The device incorporates an expandable elastomer sheath, which serves to hold the cannula vertically in place during endoscopic surgery. The device is used to create and maintain a port of entry during endoscopic surgery. It is fully disposable and is intended for single use only.

INDICATIONS	The AnchorPort® SIL Kit has applications in abdominal minimally invasive surgical procedures to include single skin incision applications and specifically where the surgeon anticipates using at least three 5mm cannula ports to establish a path of entry for operating endoscopic instruments.
NONCLINICAL TESTS SUBMITTED, REFERENCED OR RELIED UPON FOR A DETERMINATION OF SUBSTANTIAL EQUIVALENCE	Nonclinical test protocols were designed in order to test the critical performance and safety features of the device. The following bench top tests were performed in order to prove substantial equivalence and test reports are included in the filing: **Bench Data:** • Leak rate without trocars in place, after multiple trocars in place and after vigorous manipulation of trocars. • Device insertion and removal evaluation • Minimum size of skin incision • Device fixation • Rigidity / Flexibility • Size / Dimension • Sealing Instrument for maintaining insufflation • Deployment method
CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE THAT THE DEVICE IS SAFE, AS EFFECTIVE AND PERFORMS AT LEAST AS SAFELY AND EFFECTIVELY AS THE PREDICATE(S)	In vitro bench top testing has confirmed that the device is substantially equivalent in all manner of operation to the predicate devices sighted in this filing. The tests performed and submitted are those tests sighted in the above section and include method of deployment, fixation, insertion and removal forces, and maintenance of pneumoperitoneum during ordinary use and severe manipulation and incision size. In each case, the device was at least as safe and effective as the predicate. In vivo animal studies were performed, including a porcine cholecysectomy, by surgeons familiar with the predicate device(s). The in vivo testing with the AnchorPort® device demonstrates that the AnchorPort® is safe and effective. In each aspects of device performance the AnchorPort® performed as well as or better than the predicate(s) in the aspects of insertion and removal forces, anchoring and fixation and maintenance of pneumoperitoneum. The clinical outcome of the porcine cholecysectomy was a success with no adverse effects or complications. **Animal Data:** • Ease of port insertion, suturing and time to insert • Ease of insertion and withdrawal • Ability to maintain pneumoperitoneum

- Ability to manipulate instruments for laparoscopic surgery
- Ability to conduct a typical laparoscopic procedure: cholecystectomy
- Ability of anchoring plate to hold the ports in position

In conclusion, extensive in vivo (animal) testing and in vitro (bench top) testing demonstrates conclusively that the device is substantially equivalent. The device performance was validated using robust engineering test methods and living tissue models and performed at least as safely and effectively as the legally marketed devices sighted in this 510(k) submission.

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

MAY - 5 2010

SurgiQuest, Inc.
% Mr. Kourosh Azarbarzin
C.E.O.
12 Cascade Boulevard, Suite 2B
Orange, Connecticut 06477

Re: K100180
Trade/Device Name: SurgiQuest AnchorPort® Single Incision Laparoscopic Kit (SILK)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 01, 2010
Received: April 02, 2010

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. 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,

for

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

Enclosure

SURGIQUEST, INC.
510(K) NOTIFICATION
SurgiQuest AnchorPort® Optical Trocar & Cannula SIL Kit

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: K100180

Device Name: SurgiQuest AnchorPort® Single Incision Laparoscopic Kit (SILK)

Indications for Use: The AnchorPort® SIL Kit has applications in abdominal minimally invasive surgical procedures and specifically where the surgeon will make a single skin incision in order to facilitate the use of multiple trocars to establish a port of entry for operating endoscopic instruments.

Prescription Use: Yes

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

Concurrence of CDRH, Office of Device Evaluation

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100180