

K974139

JAN 28 1998

**SECTION 19: SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

**19.1 SUBMITTER INFORMATION**

- a. Company Name: LifeQuest Endoscopic Technologies, Inc.
- b. Company Address: 12961 Park Central, Suite 1300  
San Antonio, TX. 78216
- c. Company Phone: (210) 496-7332  
Company Facsimile: (210) 496-1908
- d. Contact Person: Jeffrey Scott  
Director, Regulatory Affairs  
and Quality Systems  
LifeQuest Endoscopic Technologies, Inc.
- e. Date Summary Prepared: October 30, 1997

**19.2. DEVICE IDENTIFICATION**

- a. Trade/Proprietary Name: LQET Cannula/Trocar System
- b. Classification Name: Laproscope, General and Plastic Surgery  
21 CFR 876.1500

**19.3 IDENTIFICATION OF PREDICATE DEVICE**

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
GM Engineering	Ultra-Light Cannula/ Trocar System	K942703	August 19, 1994
Gabris Surgical Corporation	GSC Seal Tight	K944103	September 12, 1994

#### **19.4 DEVICE DESCRIPTION**

The LifeQuest Endoscopic Technologies, Inc., (LQET) Cannula/Trocar System is composed of several components: cannula system, trocar/obturator, sealing caps, valve, and accessories. The cannulas are have working lengths of 40–110mm and internal diameters of 3-20mm. Single and Multi Port Caps are available. The trocars are available in pyramidal, blunt and conical shaped configurations with lengths and diameters to fir the cannulas. Both shielded and non-shielded trocar configurations are available. Cannula Accessories such as Hassan Suture Anchors, Stopcocks and Sealing Caps are available with the LQET Cannula/Trocar System. All devices that are provided sterile to the user are sterilized by ethylene oxide by the manufacturer. Reusable devices are recommended for sterilization by autoclave at the user facility.

#### **19.5 SUBSTANTIAL EQUIVALENCE**

The LQET Cannula/Trocar System is substantially equivalent to other laproscopic cannulas and trocars currently in commercial distribution by GM Engineering and Gabris Surgical Corporation in terms of intended use of providing a safe and access for instruments during laproscopic/endoscopic surgical procedures.

The fundamental technical characteristics are similar to those of the predicate devices and are listed on the comparison chart provided in this 510(k) submission.

The same materials are used in the LQET Cannula/Trocar System as used in the predicate devices. The cannulas and trocars are available in a variety of lengths and diameters. Single and MultiPort Caps are available for both the LQET System and the predicate devices.

#### **19.6 INTENDED USE**

The LQET Cannula/Trocar provides access for instruments during laproscopic/endoscopic surgical procedures.

000161

### **19.7 TECHNOLOGICAL CHARACTERISTICS**

A comparison of the technological characteristics of the LQET Cannula/Trocar System with the predicate and legally marketed devices is provided within this submission. Both the LQET Cannula/Trocar System and the predicate devices are composed of cannulas, trocars and accessories. The materials used in the devices are same and the inner diameters and working lengths are within the same range. Single Port and Multi Port Caps are available with both the LQET and the predicate device. Trocars are available with and without shields, as found in the predicate device systems. The accessories for the LQET Cannula/Trocar System, such as the Hassan Suture Anchors, are similar to the accessories available with the predicate devices. Both the LQET Cannula/Trocar System and the predicate devices are reusable.

### **19.8 PERFORMANCE DATA**

The LQET Cannula/Trocar System was subjected to performance bench testing in accordance with applicable industry and clinical standards. A study to determine the effectiveness of the recommended cleaning procedures was performed and found to be acceptable. The effectiveness of the recommended steam sterilization cycle for reusable components was performed and found to be acceptable. Several bench tests were performed to verify that the device performs as intended and that repeat sterilization of the components showed no effect to the device function.

### **19.9 510(K) CHECKLIST**

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 28 1998

Mr. Jeffrey Scott  
• Director, Regulatory Affairs and Quality Systems  
LifeQuest Endoscopic Technologies, Inc.  
12961 Park Central, Suite 1300  
San Antonio, Texas 78216

Re: K974139  
Trade Name: LQET Cannula/Trocar System  
Regulatory Class: II  
Product Code: GCJ  
Dated: October 30, 1997  
Received: November 3, 1997

Dear Mr. Scott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

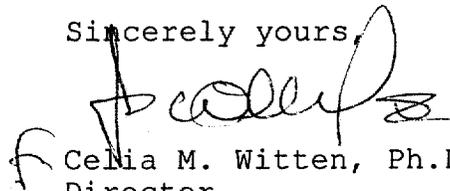
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Jeffrey Scott

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
f Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATION FOR USE**

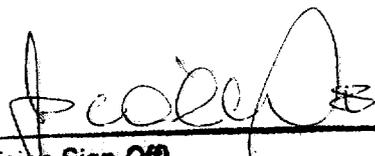
510(k) Number: ~~To Be Assigned By FDA~~ **K974139**

Device Name: **LQET Cannula/Trocar System**

Indications For Use: **The LQET Cannula/Trocar System provides access for instruments during laproscopic/endoscopic surgical procedures.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of **General Restorative Devices**  
510(k) Number **K974139**

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

000030