



K 974233

1170 Mark Avenue  
Carpinteria  
California 93013  
Tel: 805-684-0409  
Fax: 805-684-0170  
Toll Free: 888-597-6649

**510(k) SUMMARY FEB - 3 1998**

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

**Submitted by:** Ronald F. Lagerquist  
Regulatory Affairs Manager  
LySonix Inc.  
1170 Mark Avenue  
Carpinteria, CA 93013

Telephone: (805) 684-0409  
FAX: (805) 684-0170

**Date Prepared:** November 10, 1997

**Device Name:**  
Proprietary Name: LySonix Irrigation System

Common Name: Irrigation Pump

**Indication for Use:**  
The LySonix Irrigation System is intended for delivery of fluids during general surgical procedures. The device is designed to operate with the LySonix 2000 Ultrasonic Surgical System or as a stand-alone irrigation system.

The LySonix Irrigation System is not indicated for the administration of parenteral fluids, infusion of drugs or for any life sustaining purposes.

**Device Description:**  
The LySonix Irrigation System is a stand-alone version of the irrigation component of the LySonix Ultrasonic Surgical System. The system is available as a tabletop unit or as part of an integrated Operative Workstation.

**Substantial Equivalence:**  
The LySonix Irrigation System is equivalent to the irrigation component of the LySonix Ultrasonic Surgical System in terms of intended use, design, operating principles, materials and performance.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Ronald F. Lagerquist  
Regulatory Affairs Manager  
LySonix, Incorporated  
1170 Mark Avenue  
Carpinteria, California 93013

FEB - 3 1998

Re: K974233  
Trade Name: LySonix Irrigation System  
Regulatory Class: II  
Product Code: GBX  
Dated: November 10, 1997  
Received: November-12, 1997.....

Dear Mr. Lagerquist:

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.....

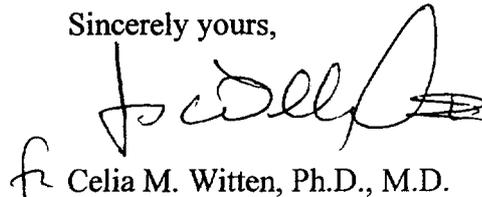
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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.

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,



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

# INDICATIONS FOR USE

Applicant: LySonix, Inc.  
510(k) Number: K974233  
Device Name: LySonix Irrigation System

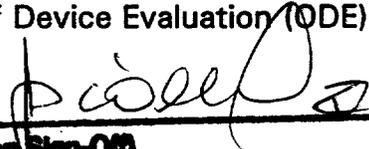
## Indications For Use:

The LySonix Irrigation System is intended for delivery of fluids during general surgical procedures. The device is designed to operate with the LySonix 2000 Ultrasonic Surgical System or as a stand-alone irrigation system.

The LySonix Irrigation System is not indicated for the administration of parenteral fluids, infusion of drugs or for any life sustaining purposes.

(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

K974233

Prescription Use X  
Per 21 CFR 801.109

OR

Over-the-Counter \_\_\_\_\_