K980454

510(k) SUMMARY

MAR 18 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
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Date Prepared: February 4, 1998

Device Name:

Proprietary Name: LySonix Aspiration Pump System

Common Name: Aspiration Pump

Indication for Use:

The LySonix Aspiration Pump System is for the suction or aspiration of fluids and tissue during surgical procedures. The device is designed to operate with the LySonix 2000 Ultrasonic Surgical System or as a stand-alone aspiration system.

Device Description:

The LySonix Aspiration Pump System is a stand-alone version of the aspiration 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 Aspiration Pump System is equivalent to the aspiration component of the LySonix Ultrasonic Surgical System in terms of intended use, design, operating principles, materials and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 1998

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

Re: K980454
Trade Name: LySonix Aspiration Pump System
Regulatory Class: II
Product Code: BTA and JCX
Dated: February 4, 1998
Received: February 5, 1998

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 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.

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,

for 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: K980454

Device Name: **LySonix Aspiration Pump System**

Indications For Use:

The LySonix Aspiration System is intended for the suction or aspiration of fluids and tissue during surgical procedures. The device is designed to operate with the LySonix 2000 Ultrasonic Surgical System or as a stand-alone aspiration system.

(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 K980454

Prescription Use X OR Over-the-Counter ____
Per 21 CFR 801.109