K972958

# 510(k) SUMMARY
# LYSONIX SUCTION/ASPIRATION CANNULAS
# LYSONIX INFUSION CANNULAS

SEP 9 1997

## I. NAME OF SUBMITTER

LySonix, Inc.
1170 Mark Avenue
Carpinteria, CA 93013

Contact person: Michael Sarrasin, JD
(805) 684-0409 phone
(805) 684-0170 fax

## II. DEVICE NAME AND CLASSIFICATION

Proprietary Name: LySonix Suction/Aspiration Cannulas (TTD Delta Scavenger Cannulas)
LySonix Infusion Cannulas (Infusion Diamond Cannulas)

Common or Usual Name: Suction/Aspiration Cannulas
Infusion/irrigation Cannulas

Classification: Class II
Endoscope and accessories; 21 CFR 876.1500
Vacuum-powered suction apparatus; CFR 880.6740

## III. PREDICATE DEVICES

The LySonix Suction/Aspiration Cannulas and Infusion Cannulas are substantially equivalent to suction and infusion cannula devices in commercial distribution by the following companies:

1. Ultra-Safe Ultrasonic Aspirator System (including suction cannulas); Morwel Corporation, Tucson, AZ; 510(k) number K962525
2. Suction Tips; Wells Johnson Company, Tucson, AZ; 510(k) number K832520
3. Endo-Pool Suction Cannulas and Irrigation Probes; Davol, Inc., Cranston, RI; 510(k) numbers K914526 and 926479
4. Newman Cannulae System; Byron Medical Corporation, Tucson, AZ; 510(k) number K862936
5. Byron Suction Tips; Byron Medical Corporation, Tucson, AZ 510(k) number K861878

## IV. DESCRIPTION

The LySonix Suction/Aspiration and Infusion Cannulas are hollow stainless steel tubes, with a blunt, bullet, or spatula-shaped tip. The cannulas are provided with an attached handle. The

Suction and Infusion Cannulas are each available in three cannula lengths and four diameters.

The LySonix Suction/Aspiration and Infusion Cannulas will be provided non-sterile

## V. INTENDED USE

The LySonix Cannulas are instruments used for suction or aspiration of fluids and tissue and for infusion of fluids during a variety of surgical procedures.

The LySonix Suction and Infusion Cannulas are inserted under the skin during various types of surgical procedures and may be connected to a suction or aspiration apparatus if desired. The Suction Cannula can then be used to suction out waste fluids or aspirate unwanted tissue. The Infusion Cannulas are used to infuse fluids such as medications or saline during surgery. The Suction/Aspiration and Infusion cannulas are not indicated for use with any specific surgical specialty, but are considered general surgical tools.

## VI. TECHNOLOGICAL CHARACTERISTICS

The LySonix Suction and Infusion Cannulas have the same technological characteristics as their predicate devices.

The materials used in all the cannulas is the same. All the manufacturers of these cannulas provide the devices in stainless steel, a biocompatible metal. The handles of the LySonix cannulas are aluminum, as are handles provided by the predicate devices.

No new technology is being introduced in the design of the LySonix Cannulas and the design of the cannulas is similar to the predicate Suction/Aspiration and Infusion Cannulas already on the market. The lengths and diameters of the LySonix Suction/Aspiration and Infusion Cannulas are within the same ranges as those of the predicate devices, and the choice of tip shapes and styles are the same standard designs as the choices provided by the predicate devices. The predicate devices provide for a variety of handles, and the handles of the LySonix cannulas do not differ in technology or design. All the devices are provided non-sterile, with some of the predicate devices also being offered as a sterile option.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. M.J. Sarrasin, J.D.
Vice President, Regulatory and Legal Affairs
LySonix, Inc.
1170 Mark Avenue
Carpinteria, California 93013

SEP 19 1997

Re: K972958
Trade Name: LySonix Suction/Aspiration and Infusion Cannulas
Regulatory Class: I
Product Code: FGY
Dated: August 8, 1997
Received: August 11, 1997

Dear Mr. Sarrasin:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

K972958

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

**INDICATIONS FOR USE**

Applicant: **LYSONIX, INC.**

510(k) Number (if known): N/A*

Device Name: **LYSONIX SUCTION/ASPIRATION AND INFUSION CANNULAS**

Indications For Use:

The LySonix Cannulas are instruments used for suction or aspiration of fluids and tissue and for infusion of fluids during a variety of surgical procedures.

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

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K972958

Prescription Use ✓ OR Over-the-Counter _____
Per 21 CFR 801.109