SEP 29 1998

K982983

Summary of Safety and Effectiveness

LSVP International Biopsy Forceps

Device Name:	LSVP International Biopsy Forceps
Common/Usual Name:	Biopsy Forceps
Classification Name:	Endoscopic biopsy instruments (Class II, Tier 1)
Predicate Devices:	Reusable Biopsy Forceps manufactured by Olympus, by Portlyn Corp., by American Endoscopy, Corp.
Submitted by:	Mr. Leon Pesotchinsky
(contact person)	LSVP International, Inc. 12755 Alto Verde Lane Los Altos Hills, Telephone: (650) 917-8100 FAX: (650) 948-7822
Summary Preparation Date:	August 19, 1998
Statement of Intended Use:	The LSVP International, Inc. Biopsy Forceps are intended specifically to collect tissue endoscopically for histologic examination.
Comparison to Predicate Devices:	The LSVP International, Inc., Biopsy Forceps are similar in design, function, and intended use to the currently marketed reusable Olympus biopsy forceps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1998

Leon Pesotchinsky
President
LSVP International, Inc.
12755 Alto Verde Lane
Los Altos Hills, CA 94022

Re: K982983
LSVP Biopsy Forceps
Dated: August 19, 1998
Received: August 26, 1998
Regulatory class: II
21 CFR 874.4480/Procode: 77 EOQ

Dear Mr. Pesotchinsky:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. Indication for Use Statement

Device name: LSVP International Biopsy Forceps

INDICATION FOR USE:

The primary indication for use of biopsy forceps is endoscopic tissue collection for histologic examination in GI/Urology, Bronchoscopy, Nasopharingoscopy, Esophagoscopy and Hysteroscopy.
Non-electric biopsy forceps are **not intended** for use in conjunction with an electrocautery unit.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982983