K992943

DEC 10 1999

MID Labs Vit Enhancer
Premarket Notification

**510(k) Summary of Safety and Effectiveness**

Contact Person: Linda Upton
MID Labs, Inc.
14477 Catalina Street
San Leandro, CA 94577
(510) 357-3952

Date Prepared: December 1, 1999

Trade Name: Vit Enhancer
Common Name: Vitrectomy Device
Classification Name: Vitreous Aspiration & Cutting Instrument
(86 HQE, 21CFR 886.4150)

Device Description/ Intended Use: Vit Enhancer is a stand alone console box with accessories, designed to be used in conjunction with a standard vitrectomy machine for vitreous cutting. The High Speed Vitreous Cutter is used with the Vit Enhancer.

Predicate Device: MID Labs SupraVit® Vitreoretinal Surgical System

Predicate Device Comparison Table

| Device Description | Vit Enhancer | SupraVit |
|---|---|---|
| 510(k) Number | current | K932669 |
| Intended Use | vitreous cutting | posterior segment ophthalmic surgery, including vitreous cutting |
| Vitreous Cutter Type | guillotine | guillotine |
| User interface | Frequency setting and display on front panel | Frequency setting and display on front panel |
| Energy source | External input pneumatic energy | External input pneumatic energy |
| Internal pressure control | Pressure regulator to control the captured pneumatic energy | Pressure regulator to control the captured pneumatic energy |
| Output valve type | Solenoid valve | Solenoid valve |
| Output frequency control | Electronic signal at user settable frequencies | Electronic signal at user settable frequencies |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

Ms. Linda M. Upton
Medical Instrument Development
14477 Catalina St.
San Leandro, CA 94577

Re: K992943
Trade Name: Vit Enhancer
Regulatory Class: II
Product Code: 86 HQE
Regulation: 886.4150
Dated: November 22, 1999
Received: November 30, 1999

Dear Ms. Upton:

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/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure II

K992943



510(k) Number (if known): K992943

Device Name: Vit Enhancer

Indications For Use:

The Vit Enhancer in conjunction with standard vitrectomy equipment is used to remove vitreous and other intraocular tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992943

(Optional Format 3-10-98)