510(k): K102222

510(k) Summary of Safety and Effectiveness

APR - 8 2011

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

Date Prepared: April 5, 2011

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

Device Description/ Intended Use: Ultimate Vit Enhancer is a standalone console box with accessories, designed to be used in conjunction with a standard vitrectomy machine (Host system) for vitreous cutting. The UVE is used with the MID Labs Vitreous Cutter labeled for use with the UVE.

Predicate Device: MID Labs AVE

Predicate Device Comparison Table

Device Description	UVE Ultimate Vit Enhancer	AVE
510(k) Number	Current	K020911
Intended Use	Vitreous cutting	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	Internal input pneumatic energy
Internal pressure control	Electronic pressure regulator	Pressure regulator to control the pneumatic energy
Output valve type	Solenoid valve	Solenoid valve
Output frequency control	Electronic signal at user scalable function of Host system frequency	Electronic signal at user settable frequencies

Performance Data: Testing and validations have demonstrated that the functional requirements and specifications have been met. Testing was conducted to measure heat generation in the vitreous cutter operated at a range of cut rates. Cutter integrity, including evaluation of the potential for metal flaking, was tested during extended exercising of the vitreous cutter at a range of cut rates. Fluid dynamics were evaluated by measuring displacement of a marker in vitreous at a range of cut rates. Requirements as outlined in the testing were met. Test data and documentation has been submitted to support system function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medical Instrument Development Laboratories, Inc.
c/o Ms. Linda Upton
Vice President
557 McCormick Street
San Leandro, CA 94577

APR - 8 2011

Re: K102222
Trade/Device Name: MID Labs Ultimate Vit Enhancer
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration and Cutting Instrument
Regulatory Class: II
Product Code: HQE
Dated: March 23, 2011
Received: March 25, 2011

Dear Ms. Upton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102222

Device name: Ultimate Vit Enhancer (UVE)

MID Labs Vitreous Cutter labeled for use with the UVE

Indications For Use:

The UVE and the MID Labs Vitreous Cutter labeled for use with the UVE are used to remove vitreous and intraocular tissue. The UVE can only be used with the MID Labs Vitreous Cutter. The UVE is used in conjunction with ophthalmic surgical equipment as a Host system (typically phacoemulsification or vitreoretinal surgical equipment).

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 SubpartD) (Part 21 CFR 801 Subpart C)

(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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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