DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 29, 2016

Medical Instrument Development Laboratories
% Ms. Brenda Balletto
VP of Regulatory and Quality
557 McCormick Street
San Leandro, California 94577

Re: K153168
Trade/Device Name: Bi-Blade Vitrectomy Cutter
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration and Cutting Instrument
Regulatory Class: Class II
Product Code: HQE
Dated: April 4, 2016
Received: April 5, 2016

Dear Ms. Balletto:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153168

Device Name
Bi-Blade Vitrectomy Cutter

Indications for Use *(Describe)*
The UVE and MID Labs Bi-Blade Vitrectomy 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 Bi-Blade Vitrectomy Cutter. The UVE is used in conjunction with ophthalmic surgical equipment as a Host system (typically phacoemulsification or vitreoretinal surgical equipment).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 8 –510(k) Summary

I. General Information

Submitter:

Medical Instrument Development Laboratories, Inc. (MID Labs)
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Contact Persons:

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Summary Preparation Date: April 22, 2016

II. Names

Trade Name:	Bi-Blade™ Vitrectomy Cutter
Common name:	Vitrectomy Device
Classification Name:	Vitreous Aspiration & Cutting Instrument (86 HQE, 21 CFR 886.4150)

III. Predicate Devices

- K102222 – Ultimate Vit Enhancer (UVE) and Accessories

IV. Product Description

The 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 host system can be any variety of commercially available devices capable of operating a vitreous cutter. The UVE is used with the MID Labs Vitreous Cutter labeled for use with the UVE.

The Ultimate Vit Enhancer (with accessories) was previously cleared via K102222.

The Vitrectomy Cutter, one of the accessories for the Ultimate Vit Enhancer and the subject of this 510(k), is a pneumatically actuated device, which supports aspiration and guillotine-style cutting functions for the purpose of removing vitreous and/or other tissues from the eye during surgery.

This 510(k) describes dimensional changes to the cutter. Specifically, a second port opening was added, and this created a second cutting edge. As the cutter moves from its retracted position to its extended position, any material in the port is cut by the first cutting edge in cooperation with the distal side of the needle port, just as in the conventional vitrectomy cutter. Unlike the conventional vitrectomy cutter, aspiration is able to continue through the opening in the side of the cutter while the cutter is in the extended position, drawing more material into the port. As the cutter moves from the extended position to the retracted position, this material is cut by the second cutting edge in cooperation with the proximal side of the needle port. Thus, there are two cuts made during a single operating cycle, as opposed to one cut for the conventional vitrectomy cutter.

V. Indications for Use

Indications for Use (same as K102222):

The UVE and the MID Labs Bi-Blade™ Vitrectomy 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 Bi-Blade™ Vitrectomy Cutter. The UVE is used in conjunction with ophthalmic surgical equipment as a Host system (typically phacoemulsification or vitreoretinal surgical equipment).

VI. Summary of Technological Characteristics

The technological characteristics of the MID Labs Bi-Blade™ vitrectomy cutter are substantially equivalent to those of the predicate device.

Characteristic	Proposed Bi-Blade™ Vitreous Cutter	K102222 UVE Ultimate Vit Enhancer and Accessories
Product Code	86- Ophthalmic Instrument, Vitreous Aspiration And Cutting, Ac-Powered	86- Ophthalmic Instrument, Vitreous Aspiration And Cutting, Ac- Powered
Regulation	• HQE, 21 CFR 886.4150	• HQE, 21 CFR 886.4150
Intended Use/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).	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).
Power source for cutter activation	Pneumatic pressure pulse	Pneumatic pressure pulse
Frequency of cutter activation	Up to 8000 pulses per minute	Up to 8000 pulses per minute
Cutting action format	Guillotine	Guillotine
Cutter return mechanism	Spring return	Spring return
Probe needle size	20 gauge or smaller	20 gauge or smaller
Cutting port format	Side port, two	Side port, one

Characteristic	Proposed Bi-Blade™ Vitreous Cutter	K102222 UVE Ultimate Vit Enhancer and Accessories
Aspiration channel	Through the cutter tubing cannula	Through the cutter tubing cannula
Patient contact material	Stainless steel	Stainless steel
Sterile product packaging and sterility method	Packaged in double Tyvek pouch, sterilized by cobalt 60 gamma radiation	Packaged in double Tyvek pouch, sterilized by cobalt 60 gamma radiation

VII. Performance Data

Testing and validations have demonstrated that the functional requirements and specifications have been met. The following tests were conducted:

- Heat Generation: Testing was conducted to measure heat generation in the vitreous cutter operated at a range of cut rates and on of all four gauges of cutters (20G, 23G, 25G, and 27G). The maximum temperature increase at the probe tip should not be greater than 10°C based on literature review: (Wu, J., Seregard, S., & Algvere, P.V. (2006). Photochemical damage of the retina. *Survey of Ophthalmology*, *51*(5), 461–481). Testing showed that the maximum temperature increase was 3°C, which is well below the maximum limit.
- Metal Flaking: Testing was performed to evaluate the potential for metal flaking in the cut range from 1500 to 8000 cpm and to verify conformance to the endurance specification for all gauges of vitrectomy Bi-Blade cutters (20G, 23G, 25G, and 27G). Acceptance criteria for the testing was that no stainless steel particle originating from the probe's cutter or needle, larger than 0.45 microns, should be present on the filter after 20 minutes of continuous use. The vitreous cutter was actuated in purified water as specified. The water was filtered and the filter examined microscopically. During testing, no stainless steel metal flakes were produced during 20 minutes of operation for all gauges tested throughout all cut rates.
- Fluid Dynamics: Testing was conducted to characterize fluid dynamic characteristics of the Bi-Blade™ Vitrectomy Cutter throughout the cutting range of 1500 to 8000 cpm, to ensure that these characteristics would not adversely affect nearby sensitive ocular structures. Testing was performed on all gauges of the Bi-Blade vitrectomy cutter (20G, 23G, 25G, and 27G). Fluid Dynamics were evaluated by measuring displacement of a marker in porcine vitreous at a range of cut rates. Video footage was reviewed and the displacement of the lens from its initial starting position to its maximum displacement was assessed using a defined unit of measurement. Testing showed that the fluid dynamics of the Bi-Blade™ vitrectomy cutter for all gauges is similar to the FDA cleared 23 gauge predicate cutter.
- Aspiration Flow Rates: Testing was conducted to characterize aspiration flow rate characteristics of the Bi-Blade™ Vitrectomy Cutter to ensure that the Bi-Blade has an equal to

or improved aspiration flow rate compared to the MID Labs previous FDA cleared predicate vitreous cutters. Testing was performed over the entire range of cutter sizes (20G, 23G, 25G, and 27G) and the entire range of cutting rate (1000 to 8000 cpm). Results of testing demonstrate that the Bi-Blade Vitrectomy Cutter, with its second open port, has less flow resistance per duty cycle and thus decreased flow interruption. The flow rate in saline fluid of the Bi-Blade cutter is relatively independent of the cutting rate. The Bi-Blade cutter is able to provide continuous aspiration even when the cutter is fully closed.

Acceptance requirements as outlined in the testing were met. Test data and documentation were submitted to support system function. Therefore, the Bi-Blade™ device is as safe, as effective, and performs as well or better than the predicate device.

VIII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the MID Labs Bi-Blade™ vitrectomy cutter is substantially equivalent to the predicate device and is safe and effective for use for the various indications for use stated.

IX. Conclusion

The MID Labs Bi-Blade™ vitrectomy cutter was found to be substantially equivalent to the predicate device.

The MID Labs Bi-Blade™ vitrectomy cutter shares identical indications for use, similar design features and functional features with, and thus are substantially equivalent to, the predicate device.