DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 22, 2017

Alcon Research, Ltd.
Karen Mudd, Ph.D.
Director, Regulatory Affairs
20511 Lake Forest Drive
Lake Forest, CA 92630

Re: K170520
Trade/Device Name: Hypervit Vitrectomy Probe, 23 Ga, Hypervit Vitrectomy Probe, 25+, Hypervit Vitrectomy Probe, 27+
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration and Cutting Instrument
Regulatory Class: Class II
Product Code: MLZ
Dated: February 16, 2017
Received: February 22, 2017

Dear Dr. Mudd:

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,

Denise L. Hampton -S

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)*
K170520

Device Name
HyperVit™ Vitrectomy Probe

Indications for Use *(Describe)*

HyperVit™ Vitrectomy Probe (23, 25 gauge)

The HyperVit™ Vitrectomy Probe is designed for use with the Constellation® Vision System and is intended to be used to remove vitreous and dissect tissue in the eye.

HyperVit™ Vitrectomy Probe (27 gauge)
The HyperVit™ Vitrectomy Probe is designed for use with the Constellation® Vision System and is intended for use as follows:

- Vitreous aspiration & cutting
- Membrane cutting & aspiration
- Lens removal
- Dissect tissue in the eye

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.

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(510)k SUMMARY

This 510(k) summary document has been prepared in accordance with Section 21 CFR 807.92.

I. Submitter of the 510(k)

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Date Prepared:	16 February 2017

II. Devices Subject to this 510(k)

Trade Names:	HyperVit™ Vitrectomy Probe
Common Name:	Vitrectomy Device
Classification Name:	Vitreous Aspiration & Cutting Instrument (21 CFR 886.4150)
Product Code:	MLZ

III. Predicate Devices

- Enhanced UltraVit® Probe K093305
- 27+ UltraVit® Probe, K110951

IV. Device Description

The HyperVit™ Vitrectomy Probe is an accessory to the Constellation® Vision System (K141065, K101285 and K063583). The HyperVit™ Vitrectomy Probe is a sterile, single-use pneumatically actuated device which supports aspiration and guillotine style cutting functions for the purpose of vitreous cutting and aspiration, as well as tissue dissection, in the eye during vitreoretinal or cataract surgery. The HyperVit™ Vitrectomy Probe is comprised of a pre-assembled hand piece and tubing. The tubing assembly interfaces with a Constellation® Vision System console by means of RFID tags at the proximal end of the probe. The HyperVit™ Vitrectomy Probe is offered in three different sizes: 23, 25 and 27 gauge.

The HyperVit™ Vitrectomy Probe is a modification of the existing UltraVit® Vitrectomy Probes currently used with the Constellation® Vision System. A port opening has been added to the cutter tip to create a second cutting edge. Thus, two cuts are made during a single operating cycle, compared to one cut for the existing UltraVit® Vitrectomy Probes. With an operating actuation speed of 10,000 cycles per minutes, the HyperVit™ Vitrectomy Probe can achieve 20,000 cuts per minute.

V. Indications for Use

HyperVit™ Vitrectomy Probe (23, 25 gauge)

The HyperVit™ Vitrectomy Probe is designed for use with the Constellation® Vision System and is intended to be used to remove vitreous and dissect tissue in the eye.

HyperVit™ Vitrectomy Probe (27 gauge)

The HyperVit™ Vitrectomy Probe is designed for use with the Constellation® Vision System and is intended for use as follows:

- Vitreous aspiration & cutting
- Membrane cutting & aspiration
- Lens removal
- Dissect tissue in the eye

VI. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the HyperVit™ Vitrectomy Probe are substantially equivalent to those of the predicate device, as shown in the table below.

Characteristic	**Predicate Devices** **K093305, Enhanced UltraVit Probe (23 and 25 gauge)** **K110951, 27+ UltraVit Probe (27 gauge)**	**HyperVit Vitrectomy Probe (23, 25 and 27 gauge)**
Regulation	886.4150	Same
Intended use / Indications for use	**K093305, Enhanced UltraVit Probe (23 and 25 gauge):** The ALCON® Enhanced UltraVit® Probe is designed for use with the Constellation® Vision System and is intended to be used to remove vitreous and dissect tissue in the eye.	**23 and 25 gauge:** The HyperVit™ Vitrectomy Probe is designed for use with the Constellation® Vision System and is intended to be used to remove vitreous and dissect tissue in the eye.
	K110951, 27+ UltraVit Probe (27 gauge): • Vitreous aspiration & cutting • Membrane cutting & aspiration • Remove a crystalline lens • Dissect tissue in the eye (The 27 UltraVit Probe is intended to be used with the Alcon Constellation Vision System)	**27 gauge:** The HyperVit™ Vitrectomy Probe is designed for use with the Constellation® Vision System and is intended for use as follows: • Vitreous aspiration & cutting • Membrane cutting & aspiration • Lens removal • Dissect tissue in the eye
Power source for cutter activation	Forward and return pneumatic pressure pulses	Same
Probe needle gauge	23, 25, 27	Same
Cutting action format	Guillotine	Same
Frequency of cutter activation	Up to 15,000 pulses per minute	Up to 10,000 pulses per minute
Cutting port format	Side port, one	Side port, two
Cutting rate	Up to 15,000 cuts per minute	Up to 20,000 cuts per minute
Aspiration channel	Through the cutter tubing cannula	Same
Patient contact material (direct or through fluid path)	Stainless steel	Same
Overall length of probe (nominal)	3.3”	Same
Single-use / Reusable	Single use only	Same
Shelf-life	Two years	Same
Sterile product packaging	Tyvek pouch	Same
Sterility method	EtO-sterilized	Same
Gauge identifier	Color coded and molded in the product	Same
Connector	RFID (connectors for pneumatic lines and luer connectors for aspiration line)	Same

VII. Performance Data

Testing and validations have demonstrated that the functional requirements and specifications have been met. Therefore, the HyperVit™ Vitrectomy Probe is as safe and effective as the predicate device. An overview of key performance tests conducted is provided below:

Mechanical Testing

- Cut Quality: Testing was conducted on the vitreous cutting surfaces in order to verify that the forward and return cutting surfaces met the same acceptance criteria for cut quality and cut reliability as the predicate device. Results show that the probe met the acceptance criteria and, therefore, have the same cut quality as the predicate device.
- Aspiration Flow: The aspiration flow characteristics of the HyperVit™ Vitrectomy Probe at the default vacuum settings were characterized and compared with the predicate device. The flow characteristics of the HyperVit™ Vitrectomy Probe at the default vacuum setting were similar to those of the predicate device as a result of the identical dimensions of the fluid path (e.g., cutter and aspiration tubing). Therefore, the aspiration flow is equivalent to the predicate device.
- Heat Generation: Testing was conducted to measure the temperature increase at the vitreous cutter tip operated at 150% of HyperVit™ Vitrectomy Probe maximum speed. Testing showed that the maximum temperature increase was 0.8°C throughout 30 minutes of operation; this is less than the maximum allowed temperature increase at the probe tip of no more than 10°C, based on literature review (Ref: Wu et al., Photochemical damage of the retina. Survey of Ophthalmology, 51(5), 461–481, 2006).
- Metal Particulates: Testing was performed to evaluate whether metal particulates were generated by the HyperVit™ Vitrectomy Probe during operation. The probe was actuated at the maximum 10,000 cycles per minute in a water container. After running the test continuously for 20 minutes, the filter in the container was microscopy-examined for metal particulate and no particulates were detected, thus meeting the acceptance criteria.

VIII. Safety and Effectiveness Information

A review of the indications for use and technical characteristics demonstrates that the HyperVit™ Vitrectomy Probe is substantially equivalent to the predicate devices and is safe and effective for use for the stated indications for use.

IX. Conclusion

The HyperVit™ Vitrectomy Probe was found to be substantially equivalent to the predicate device.

The HyperVit™ Vitrectomy Probe shares identical indications for use, similar design features and functional features with the predicate device, and thus is substantially equivalent to the predicate device.