May 4, 2022

Vista Ophthalmics LLC
% Debe Deck
SVP, Program Management & Client Services
Regulatory Pathways Group Inc.
340 S. Lemon Ave, #2471
Walnut, CA 91789

Re: K220030
Trade/Device Name: Vista Ophthalmics Vitrectomy Probe
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration And Cutting Instrument
Regulatory Class: Class II
Product Code: MLZ
Dated: March 22, 2022
Received: March 24, 2022

Dear Debe Deck:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anjana Jain, PhD
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K220030

Device Name
Vista Ophthalmics Vitrectomy Probe

Indications for Use *(Describe)*

The Vista Ophthalmics vitrectomy probe is intended to be used to remove vitreous and dissect tissue in the eye as follows:
- Vitreous aspiration & cutting
- Membrane cutting & aspiration
- Lens removal
- Dissect tissue in the eye

The Vista Ophthalmics probe is designed as a stand-alone handpiece for use with ophthalmic surgical systems having pneumatically driven vitreoretinal functionality.

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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## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

| | |
|---|---|
| **APPLICANT:** | Vista Ophthalmics<br>23510 Kingsland Blvd. #200<br>Katy, TX 77494 |
| **OFFICIAL CORRESPONDENT:** | Debe Deck<br>Regulatory Pathways Group Inc.<br>(949) 375-4387<br>ddeck@regulatorypathways.com |
| **DATE SUMMARY PREPARED:** | May 2, 2022 |
| **TRADE NAME:** | Vista Ophthalmics Vitrectomy Probe |
| **COMMON NAME:** | Same |
| **DEVICE CLASSIFICATION / CODE** | Class II<br>886.4150 Vitreous aspiration and cutting instrument<br>MLZ |
| **PREDICATE DEVICE:** | Alcon Hypervit Vitrectomy Probe<br>Alcon, Inc.<br>K170520 |
| **REFERENCE DEVICE:** | Vision Care ProCare Plus<br>Vision Care Devices, LLC.<br>K120170 |

### DEVICE DESCRIPTION

The Vista vitrectomy probe 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 anterior and posterior ophthalmic procedures. The Vista vitrectomy probe is offered in a two port bi-blade configuration.

The Vista vitrectomy probe utilizes a pressured air pulse to drive the cutting action. The pressure pulse originates from the operational system of choice and distends or expands a silicone rubber diaphragm inside the handpiece. The pressure pulse fills the pressure chamber of the vitrector, actuating the axial extension of the inner-cutting tube to produce a guillotine-type cutting motion. A vacuum originating from the operational system of choice draws biological materials (tissue and fluid) into the outer cutting port area of the portion of the cannula that is inserted into the patient's eye. The vacuum-drawn material entering the outer needle port is then resected by the inner-cutter as it travels down the inside diameter of the outer needle. Once the inner-cutter resects (guillotines) the material as it crosses the distal end of the outer needle port cutting edge,

the material is aspirated through the inside diameter of the inner-cutting tube. The material continues to be aspirated through the handpiece and into a collection chamber of the vitrectomy system selected for use with the Vista vitrectomy accessory.

### INDICATIONS FOR USE

The Vista Ophthalmics vitrectomy probe is intended to be used to remove vitreous and dissect tissue in the eye as follows:

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

The Vista Ophthalmics probe is designed as a stand-alone handpiece for use with ophthalmic surgical systems having pneumatically driven vitreoretinal functionality.

### TECHNOLOGICAL CHARACTERISTICS COMPARISON

The technological characteristics of the Vista vitrectomy probe are substantially equivalent to those of the predicate device, the Alcon Hypervit (K170520), and reference device, the VisionCare (K120170). These devices share the similar actuation energy source (pneumatic pulses) and cutting speeds, the same type of aspiration source (low vacuum), and the same mechanism of action (guillotine style cutting).

The Vista vitrectomy probe incorporates a biocompatible chromium coating on the inner cutter surface to allow for low-force entry of the Vista Ophthalmics handpiece into the eye without the need for other blades or entry system accessories.

Table 1 on the following page provides a comparison of the technological characteristics of the proposed Vista vitrectomy probe and the substantially equivalent predicate device: the Alcon Hypervit (K170520).

**TABLE 1**
**TECHNOLOGICAL COMPARISON OF THE VISTA VITRECTOMY PROBE TO THE PREDICATE DEVICE**

| Characteristic | Vista Ophthalmics Vitrectomy Probe (Proposed device) | HyperVit Vitrectomy Probe K170520 (Predicate Device) |
|---|---|---|
| **Regulation/Product Code** | 886.4150 / MLZ | 886.4150 / MLZ |
| **Intended use/Indications for use** | The Vista Ophthalmics vitrectomy probe is intended to be used to remove vitreous and dissect tissue in the eye as follows:<br>• Vitreous aspiration & cutting<br>• Membrane cutting & aspiration<br>• Lens removal<br>• Dissect tissue in the eye<br><br>The Vista Ophthalmics probe is designed as a stand-alone handpiece for use with ophthalmic surgical systems having pneumatically driven vitreoretinal functionality | 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 (23 and 25 gauge)<br><br>The HyperVit™ Vitrectomy Probe is designed for use with the Constellation® Vision System and is intended for use as follows: (27 gauge)<br>• Vitreous aspiration & cutting<br>• Membrane cutting & aspiration<br>• Lens removal<br>• Dissect tissue in the eye |
| **Power source for cutter activation** | Forward pneumatic pressure pulses with spring return | Forward and return pneumatic pressure pulses |
| **Probe needle gauge** | 27 | 25, 27 |
| **Cutting port format** | Side port, 2 | Side port, 2 |
| **Cutting action format** | Guillotine | Guillotine |
| **Cutter activation speed** | 11,000 max cycles/minute | 10,000 max cycles/minute |
| **Cutting speed** | 22,000 max cuts/minute | 20,000 max cuts/minute |
| **Aspiration means** | Through inner cutter tubing | Through inner cutter tubing |
| **Patient contacting material** | Stainless steel w/ ME-92 coating | Stainless steel |
| **Overall length of probe, nominal** | 55 mm | 84 mm |
| **Single-use / Reusable** | Single use only | Single use only |

| Characteristic | Vista Ophthalmics Vitrectomy Probe (Proposed device) | HyperVit Vitrectomy Probe K170520 (Predicate Device) |
|---|---|---|
| **How Supplied** | Sterile | Sterile |
| **Sterile product packaging** | Tyvek pouch | Tyvek pouch |
| **Method of Sterilization** | Gamma | EtO-sterilized |
| **Shelf-life** | 3 years | 2 years |

## PERFORMANCE DATA

The descriptive characteristics of the Vista vitrectomy probe have been fully defined and are adequate to ensure equivalence to the predicate device. All validation processes have demonstrated that the functional requirements and finished device specifications are met.

An overview of key performance tests conducted with the finished Vista probe and reference device is provided below.

- Biocompatibility testing of the Vista vitrectomy probe in accordance with ISO 10993-01 including Cytotoxicity (per ISO 10993-5), Sensitization (per ISO 10993-10), Ocular Irritation (per ISO 10993-10), Systemic toxicity (per ISO 10993-11) and Material Mediated Pyrogenicity (per ISO 10993-11).
- Sterilization conditions were substantiated for the Vista vitrectomy probe to provide a Sterility Assurance Level of $10^{-6}$, in accordance with ISO 11137. Bioburden testing.
- Bacterial Endotoxin testing (BET) was performed on the Vista vitrectomy probe in accordance with ANSI/AAMI ST72.
- Packaging qualification was performed with the reference device as part of the transportation and environmental conditioning studies to demonstrate that package and seal integrity requirements were met.
- Accelerated shelf life testing and device stability testing was performed on a reference device as part of the packaging validation test program for the sterile device to establish the expiration date for the Vista vitrectomy probe.
- Post-aging transportation testing (per ISTA 6) and device stability testing of the Vista vitrecotmy probe confirmed that performance specifications were met.
- Performance evaluations were successfully performed with the finished Vista Vitrectomy probe including material cutting and aspiration and cut speed, validations for the resistance of cannula deformation, metal flaking as well as cannula penetration force testing. Additionally, the operating temperature limits of the cannula tip were simulated in worst-case operations.

## CONCLUSION

The Vista vitrectomy probe meets all product design requirements and applicable standards. The device has the same intended use and key technological characteristics as the predicate devices. Therefore, the device has been shown to be substantially equivalent to the predicate devices.