Health Canada Santé Canada

Medical Devices Directorate
11 Holland Ave, 2nd Floor
Address Locator: 3002A
Ottawa, ON K1A 0K9

20 December 2023

Application No. 367993

George Aubrey
Managing Partner
Vis, Llc
2800 Dallas Parkway, Suite 100
Plano TX 75093
United States

Investigational Testing Authorization - Class II

Dear George Aubrey:

This is in reference to your application for authorization to conduct investigational testing in Canada, received on 4 October 2023, and submitted pursuant to Part 3 of the *Medical Devices Regulations*. This pertains to the following:

Protocol: Vision Improvement for Patients with Age-Related Macular Degeneration

Number: VIS #Opti-K 001 **Date:** 21 November 2023

Objectives: This study is being performed to assess the safety and efficacy of the VIS Opti-K Low Vision Aid Device in providing vision improvement to patients with age-related macular degeneration.

Device: Opti-K Low Vision Aid Device

No. of Devices: One (1)

No. of Patients: Two hundred (200)

The information has been reviewed and VIS, LLC is hereby authorized under Section 83 of the *Medical Devices Regulations* to sell the subject device for investigational testing to the investigators as listed in the attached Appendix 1.

Please note that authorization of this investigational testing should not be construed as agreement by Health Canada that the data obtained from the testing will be considered sufficient to meet licensing requirements for the devices used in this study.

Sections 86, 87 and 88 of the *Medical Devices Regulations* impose additional requirements regarding the advertisement, record keeping and labelling of devices involved in investigational testing. Please advise the Bureau of any changes to the device, protocol or list of investigators. Any changes to the device or protocol that fall outside the scope of the risk assessment of this protocol will require a new application.

Consistent with Health Canada's 2007 Notice concerning registration and disclosure of clinical trial information for therapeutic products (including drugs and devices), sponsors of investigational testing of medical devices are

reminded to register their investigational testing within 21 days of the start of the investigation, using a publicly available registry that conforms to international standards for registries such as: Clinicaltrials.gov (www.clinicaltrials.gov); Current Controlled Trials (www.controlled-trials.com).

Yours sincerely,

Emily Hollink
A/ Executive Director
Medical Devices Directorate

Attach.
EH, mb

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Appendix 1 - List of Investigators and Institutions **Application No. 367993**

Date: 20 December 2023

Investigators' Names and Addresses of Institutions
Dr. Raymond Stein Arthur Bochner Eye Institute, 40 Prince Ave, Toronto, ON, M5R 1A9