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

Vision Care Ophthalmic Technologies, Ltd.
c/o Judy F. Gordon, D.V.M.
Regulatory Consultant
14395 Saratoga Avenue #150
Saratoga, California 95070

JUL 1 2010

Re: P050034
Implantable Miniature Telescope™ (by: Dr. Isaac Lipshitz) (IMT) Models Wide Angle 2.2X and Wide Angle 2.7X
Filed: September 9, 2005
Amended: November 8, 2005, February 2, April 26, June 6 and 27, and July 25, 2006, February 7, March 20, May 15, November 1, and December 20, 2007, March 3, September 3, October 6 and 15, November 4 and 19, and December 22, 2008, January 8, May 7, September 17, October 13, and December 28, 2009, February 17 and 19, March 19, April 2 and 9, and May 10, 2010
Procode: NCJ

Dear Dr. Gordon:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the IMT Models Wide Angle 2.2X and Wide Angle 2.7X. This device is indicated for monocular implantation to improve vision in patients greater than or equal to 75 years of age with stable severe to profound vision impairment (best corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotomas associated with end-stage age-related macular degeneration.

Patients must:

- have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography
- have evidence of visually significant cataract (≥ Grade 2)
- agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists (optometrist or occupational therapist) in the use of an external telescope sufficient for patient assessment and for the patient to make an informed decision
- achieve at least a 5-letter improvement on the ETDRS chart with an external telescope
- have adequate peripheral vision in the eye not scheduled for surgery
- agree to participate in postoperative visual training with a low vision specialist.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 2 years.

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" **(please use this title even if the specified interval is more frequent than one year)** and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you have agreed to provide the following data in post-approval study reports (PAS). Two copies, identified as "PMA Post-Approval Study Report" and being the applicable PMA reference number, should be submitted to the address below.

Post-Approval Studies:

1. *Extended follow-up of the Premarket Cohort Population* (IMT-002-LTME). Per the complete protocol in P050034/A028 as well as agreement by email dated May 19, 2010, this continued follow-up of individuals in the long-term follow-up cohort (5 years post-operatively) will be conducted to provide additional long-term (up to 8 years) safety data for patients receiving VisionCare's Implantable Miniature Telescope (IMT). This prospective, observational, open-label, single-group cohort safety study anticipates enrolling 70 subjects from the PMA pivotal clinical study who will be examined at the 84-month and 96-month anniversary of the date of surgery in Protocol IMT-002. Slit

lamp and funduscopic examination findings, as well as best spectacle-corrected distance visual acuity, intraocular pressure, endothelial cell density (ECD) and ocular adverse events will be collected. The study endpoints include: adverse events, persistent vision-impairing corneal edema, and corneal transplantation assessed at each follow-up visit. The study protocol has limited power to test statistical hypotheses; however, the long-term rates of the study endpoints can be determined.

2. *New Enrollment Study* (PAS-01): Per agreement dated May 19, 2010 (e-mail version of protocol dated 5/11/10 and email dated 5/18/2010) this study will address the following question: Is the five-year cumulative incidence of persistent vision-impairing corneal edema (persistent loss of best corrected distance visual acuity >2 lines from pre-surgery baseline) less than 17%? To examine this question, a multicenter, prospective, open label, single group assignment cohort study for safety, consecutively will enroll 770 pre-surgical subjects aged 75 years and older with severe to profound vision impairment caused by end-stage age-related macular degeneration and a cataract. The subjects enrolled and undergoing implantation of the IMT will be followed for a total of 5 years with approximately 6 follow-up visits during the first year followed by annual visits thereafter for the next four years. At each visit slit lamp and funduscopic findings, best spectacle-corrected distance visual acuity, intraocular pressure, and ocular adverse events will be collected. Within a sub-sample of the cohort (n=150), ECD will be measured at baseline, 3-months, 12-months, and annually thereafter. The primary study outcome will be the occurrence of persistent vision-impairing corneal edema as previously defined. Other study endpoints for safety include all adverse events over the course of follow up, surgical complications, corneal transplantation, retinal detachment, device explant and malfunction.

Informed Consent Process:

3. As a part of your formal decision process, you must distribute your approved Acceptance of Risk and Informed Decision Agreement, which will serve as a collective source of information (including patient labeling) for the patient. Both the physician and the patent are intended to sign designated sections in order to best assure that a patient has obtained the labeling in an adequate enough time prior to surgery to read it and has understood the risks and other information associated with the Implantable Miniature Telescope™.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Within 30 days of your receipt of this letter, you must submit two PMA supplements that include a complete final protocol for each of your post-approval studies. Your PMA supplements should be clearly labeled as a "Post-Approval Study Protocol: 002-LTME" and "Post-Approval Study Protocol: PAS-01", submitted in triplicate to the address below. Please reference the PMA

number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2).

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at

www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

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If you have any questions concerning this approval order, please contact Mr. Don Calogero at 301-796-6860.

Sincerely yours,

Nathan C. Lake MD PhD for

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health