DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 29, 2016

ReVision Optics, Inc.
Mr. R. Michael Crompton
Vice President, Regulatory Affairs & Quality Assurance
25651 Atlantic Ocean Drive, Suite A-1
Lake Forest, CA 92630

Re: P150034
Raindrop® Near Vision Inlay
Filed: October 19, 2015
Amended: November 6, 2015; March 30, and April 22, 2016
Procode: LQE

Dear Mr. Crompton:

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 Raindrop® Near Vision Inlay. This device is indicated for intrastromal implantation to improve near vision in the non-dominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent of (MRSE) +1.00 diopters (D) to -0.50 D with less than or equal to 0.75 D of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 D to +2.50 D of reading add. 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 three (3) years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

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" 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. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

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 must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. The final report will be submitted to FDA within three (3) months of study completion. Two (2) copies of each report, identified as an "ODE Lead PMA Post-Approval Study Report" or “OSB Lead PMA Post-Approval Study Report” in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

1. ODE Lead PMA Post-Approval Study – A Multicenter Postmarket Surveillance Study to Evaluate the Long Term Safety of the Revision Optics, Inc. Raindrop® Near Vision Inlay in Emmetropic Subjects: The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The Multicenter Postmarket Surveillance Study to Evaluate the Long Term Safety of the Revision Optics, Inc. Raindrop® Near Vision Inlay in Emmetropic Subjects (Protocol P15-0065-X4 received via e-mail on May 25, 2016) is a single-arm, prospective, multicenter, observational study to evaluate the long-term safety of the Raindrop® Near Vision Inlay in emmetropic patients who were previously enrolled in the single-arm, prospective, multicenter, interventional pivotal trial conducted under IDE G090149 to support the PMA.

Subjects from G090149, whether currently enrolled or not, who have not passed the 60-month post-operative inlay implantation window or the 24-month post-removal window, whichever is longer after initial implantation, will be recruited. Subjects will be followed until 60 months after initial inlay implantation, or 24 months after removal, whichever is longer.

The endpoints include the rate of persistent loss of 2 lines or more of best-corrected distance visual acuity at the last available visit from pre-operative baseline with a target of less than 5%, and the rate of secondary surgical interventions over 60 months postoperatively with a target of 10% or less.

2. OSB Lead PMA Post-Approval Study – *Raindrop® Near Vision Inlay New Enrollment Study*: The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval. The Raindrop® Near Vision Inlay New Enrollment Study is designed to evaluate the Raindrop® Near Vision Inlay in terms of long term safety, the effect of prescribed steroid medication regimens, and the impact of surgical parameters used during implantation on patient safety outcomes. This is a prospective, single-arm, multi-center registry study of newly enrolled patients.

   The study will enroll at least 528 eyes from 528 phakic, presbyopic patients (unilateral implantation in the non-dominant eye) between the ages of 41 and 65 years at up to 30 sites, to ensure that at least 422 patients (assuming an overall attrition rate of 20%) will be available for long-term follow-up at 60 months after implantation.

   The post-approval study will be conducted in two phases:

   Phase One:
   Phase one will occur prior to initiating enrollment for phase two of the post-approval study. In phase one, a questionnaire will be developed to elicit the reason(s) for device explantation including the experience of visual symptoms. The questionnaire will be assessed qualitatively through concept elicitation and cognitive debriefing interviews, ensuring concept saturation has been reached. The qualitative assessment will evaluate:

   (1) The clarity of the items within the instrument
   (2) How the respondents interpret the item(s)
   (3) Ease of completion of the patient-reported outcomes (PROs)
   (4) The comprehensiveness of the PROs
   (5) The appropriateness of the format, response scales, and recall period used in the PROs.

   Phase Two:
   Phase two will involve the conduct of the new-enrollment post-approval study, which will begin after results from phase one are accepted by the FDA. The questionnaire developed in phase one of the study will be assessed quantitatively and formally

administered during phase two as a nested component of the post-approval study. The quantitative questionnaire assessment will evaluate the psychometric properties of the most up-to-date questionnaire including evaluations of (if appropriate):

(a) Internal consistency reliability
(b) Test-retest reliability (in stable patients)
(c) Clinical validity
(d) Known groups validity
(e) Item Response Theory and/or Factor Analysis to understand the factor structure.

The co-primary endpoints for the post-approval study test the following hypotheses:

1. That fewer than 5% of eyes have a persistent (present at the subject's last visit) loss of two (2) lines or more of best corrected distance visual acuity (BCDVA) at 60 months after inlay implantation, or 24 months after removal, whichever is longer, with a one-sided alpha level of 0.025.
2. Fewer than 10% of eyes underwent device removal over the 60-months of follow-up with a one-sided alpha level of 0.025.

Both of the alternative hypotheses should be met in order to determine the safety of the inlay.

The secondary endpoints include:

1. The rate of secondary surgical interventions overall and by type (e.g. exchange); and
2. The rate of adverse events (especially those resulting in BCDVA loss of two or more lines) categorized as ocular, device and/or procedure related, unanticipated, or other.

Additional clinical observations include:

- Operative surgical parameters [spot/line separation, target flap depth (absolute value and as percentage of central corneal thickness), etc.]
- Refractive stability (manifest refractive spherical equivalent)
- Slit lamp observation (especially haze development, grading, and recurrence rate)
- Assessment of dry eye syndrome
- Intraocular pressure
- Additional steroid medication regimens prescribed (including number of patients, length of treatment, and reasons for treatment) and rate of sequelae due to chronic use
- Information about cataract development and management
- Uncorrected near visual acuity
- Ease of assessment of the retina.

The observed rate of persistent BCDVA loss of two or more lines and that of inlay removal during the 60-month follow-up period will be compared to their performance goals based on the exact binomial distribution with one-sided significance level of 0.025. All ocular adverse events (including secondary surgical interventions) will be summarized by the number and percent of patients reported with the corresponding events. The summary will also be stratified by device and/or procedure relationship. The number and percent of patients with haze and those with recurrent haze will also be provided. Descriptive statistics will be calculated for all other clinical parameters.

Assessments of patients will be performed at the following timepoints: preoperative visit (day -90 to -1), the day of operation (day 0), day 1, 1 week, and at 1, 3, 6, 9, and 12 months, and annually thereafter for 60 total months of follow-up. Explanted patients will be assessed at 1 day, 1 week, and at 1, 3, 6, 12, and 24 months after explant.

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your OSB Lead PMA Post-Approval Study. Your PMA supplement should be clearly labeled as OSB-Lead PMA Post-Approval Study Protocol as noted above and 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.

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. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a 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" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

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 Food and Drug Administration, Dockets Management Branch, (HFA-305), 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 final labeling. Final 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 labeling is identical to the labeling approved in draft form. If the final 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 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Jeffrey Brocious at (301)796-6860 or Jeffrey.brocious@fda.hhs.gov.

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