November 22, 2017

RxSight, Inc.
Ms. Maureen O'Connell
Vice President, Clinical and Regulatory Affairs
100 Columbia
Aliso Viejo, CA 92656

Re: P160055
Trade/Device Name: Light Adjustable Lens (LAL) and Light Delivery Device (LDD)
Filed: January 12, 2017
Amended: February 28, and July 31, 2017
Product Code: PZK

Dear Ms. O'Connell:

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 Light Adjustable Lens (LAL) And Light Delivery Device (LDD) system. This system is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag, in adult patients:

- With pre-existing corneal astigmatism of ≥ 0.75 diopters
- Without pre-existing macular disease

The system also reduces the likelihood of clinically significant residual spherical refractive errors.

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 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 the 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 PMA 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 the PAS listed below. Separate PAS Progress Reports must be submitted for the study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. Two (2) copies of each report, identified as an "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.

The LAL/LDD Postmarket RCT is designed to evaluate the following postmarket questions:
1. What is the rate of Endothelial Cell Density loss (ECL) for patients with the LAL/LDD?
2. What is the rate of retinal damage caused by UV treatment with the LDD that may not be detected by routine post-operative testing?
This is a two phased study that will include Phase A and Phase B. The primary objective of Phase A is to develop a patient reported outcome (PRO) instrument that will assess erythropsia after LDD light treatments. This part of the study is a non-interventional, qualitative research, cognitive debriefing interview study that may use patients treated using the marketed device.

Phase B is a prospective, randomized, multicenter, post approval study of the LAL and LDD to be conducted at approximately 5 clinical sites. It will begin after development of the PRO in Phase A is complete and has been accepted by FDA. This is a new enrollment study that is expected to last up to 24 months and include up to 11 study visits. 540 subjects will be randomized in a 2:1 ratio to receive either the LAL or a monofocal IOL (Control).

The following clinical examinations will be performed:

- Uncorrected visual acuity
- Manifest refraction
- Best spectacle corrected visual acuity
- Spectral Domain optical coherence tomography (SD-OCT)
    - SD-OCT scans of the macular region will be performed, covering approximately 10 degrees of eccentricity in all horizontal, vertical, and principal diagonal meridians.
- Specular microscopy
- City University Color Test
- Slit lamp exam
- Erythropsia Assessment
- Erythropsia PRO
- Fundus exam
- Fundus photos
- Multifocal electroretinogram (ERG) (if needed)
- Short-Wave Automated Perimetry (SWAP) (baseline and if needed post light treatment)

A reading center will read both the endothelial cell count images and the SD-OCT images.

ERG and SWAP will be performed in eyes that meet any of the following criteria:

- Significant erythropsia (either through in-office testing or reported by the patient),
- Has a tritan anomaly (when there was none pre-treatment), or an increase in tritan anomaly (tritan > 1) on Part II of the 3rd Edition City University Color Vision Test (CUT) at any time after light treatment,
- Any level of erythropsia or tritan anomaly at 3 months or later,
- Has an unexplained loss of acuity ≥2 lines compared to pre-light-treatment,
  or
- Shows changes consistent with phototoxicity on the OCT (including, e.g., evaluating outer retinal hyper or hypo reflectivity).

The primary safety endpoints are mean rate of endothelial cell density loss at postop month 6 compared to preoperatively compared between the LAL and Control group, and percent of LAL eyes with UV retinal damage at postop month 6. UV retinal damage will be diagnosed if the SD-OCT scan demonstrates disruption of the inner/outer segment junction, the outer nuclear layer, or retinal pigment epithelial layer. Subjects will be followed for 6 months postoperatively as follows: preoperative, operative, postop day 1, postop week 1, postop week 3, adjustment #2 visit (if needed) (LAL only), lock-in #1 (LAL only), lock-in #2 (LAL only), postop months 1-2, and postop month 6. If a study eye is diagnosed with UV retinal damage, an additional follow-up exam will be added at 12 months postoperatively.

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.

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage http://www.fda.gov/devicepostapproval.

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).

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described above. Your PMA supplement should be clearly labeled as an "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.

Before making any change affecting the safety or effectiveness of the PMA 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" http://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 http://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 http://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 http://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 Bennett Walker at 301-796-5093 or Bennett.Walker@fda.hhs.gov.

Sincerely,

Randall G. Brockman -S

for William H. Maisel, MD, MPH
Acting Director, Office of Device Evaluation
Deputy Center Director for Science
Office of Device Evaluation
Center for Devices and Radiological Health