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

December 22, 2016

Alcon Research, Ltd.
Ms. Amy Tezel
Global Head, Regulatory Affairs
6201 South Freeway (tc-45)
Fort Worth, TX 76134-2099

Re: P040020/S049
Trade/Device Name: Acrysof® IQ ReSTOR® +3.0 D Multifocal Toric Intraocular Lenses
Models: SND1T3, SND1T4, SND1T5 and SND1T6
Filed: August 14, 2013
Amended: December 19, 2013; May 7, 2014; May 30, 2014; December 18, 2014;
January 7, 2016, and August 2, 2016
Product Code: MFK

Dear Ms. Tezel:

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) supplement for the Acrysof® IQ ReSTOR® +3.0 D Multifocal Toric Intraocular Lenses (Models: SND1T3, SND1T4, SND1T5 and SND1T6) for expanding the indications to include visual correction of pre-existing corneal astigmatism. This device is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision, reduction of residual refractive cylinder and increased spectacle independence. The lens is intended to be placed in the capsular bag. We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device as modified 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). FDA has determined that this restriction on sale and distribution is 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 5 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 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. 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.

OSB-Lead PMA Post-Approval Study: Post Approval Study for the AcrySof® IQ ReSTOR® +3.0 D Toric IOLs to Assess Post-Surgical Intraocular Inflammation: The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval. According to the protocol outline received via email on November 21, 2016, you have agreed to conduct a study as follows:

The AcrySof® IQ ReSTOR® +3.0 D Toric Post Approval Study is designed to evaluate the rate of post-surgical intraocular inflammation (based on a specified case definition) observed

following implantation of an AcrySof ®IQ ReSTOR® +3.0 D Toric IOL, compared to the rate of post-surgical intraocular inflammation (based on ICD-9 codes) observed from the 2011-2013 Medicare Beneficiary Encrypted Files (BEF). The study is intended to assess the safety of the approved device, and will be conducted in two phases. The two phases may be conducted in parallel.

Phase A:
Phase A of the study consists of a multi-center active surveillance study in 3,000 eyes that have been implanted with an AcrySof® IQ ReSTOR® +3.0 D Toric IOL for up to 180 days. The primary endpoint is the rate (per 1,000) of post-surgical intraocular inflammation (based on the predefined case definition) reported within a 180 day post-surgical period following implantation of AcrySof® IQ ReSTOR® Toric IOLs. The case definition of post-surgical intraocular inflammation is as follows: Exacerbated intraocular inflammation within 180 days after IOL implantation as indicated by:

- ≥ 3+ aqueous cell within the first two weeks post-op (collected on Forms 1 and 2 or at an unscheduled visit between Form 0 and Form 2), and/or
- ≥ 2+ aqueous cell between 14 days and 60 days post-op (collected on Form 3 or at an unscheduled visit between Form 2 and Form 3), and/or
- ≥ 1+ aqueous cell after 60 days post-op or later (collected on Form 4 or at an unscheduled visit between Form 3 and Form 4)

There is no study hypothesis.

A minimum of 3,000 eyes will be enrolled. Patients will be followed for 180 days postoperatively. Study visits/assessments will occur at 1 day, 1-2 week, 1-2 month, and 3-6 month postoperatively, according to the premarket post op assessment schedule (Forms 1 through 4).

Phase B:
Phase B of the study consists of a secondary data analysis of the 2011-2013 Medicare Beneficiary Encrypted Files (BEF). All cataract surgeries reported in 2011 through 2013 Medicare BEF will be reviewed to determine the background rate of post-surgical intraocular inflammation (based on the associated coding of endophthalmitis, uveitis, postsurgical intraocular inflammation or other related codes) within a 180 day post-surgical period following implantation of an intraocular lens. It is anticipated that there will be approximately 180,000 surgeries available to estimate the background rate.

Interim reports will be submitted to the FDA for review (beginning at PMA approval date) every six months for the first two years, and annually thereafter until study completion. The final report must be submitted to the FDA within three months of study completion.

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 Don Calogero at 301-796-6483 or Don.Calogero@fda.hhs.gov.

Sincerely,

John W. Sheets Jr -S

John W. Sheets Jr., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health