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

Rosanne Yetemian, Ph.D.
Regulatory Affairs Specialist
Abbott Medical Optics Inc. (AMO)
1700 East Saint Andrew Place
Santa Ana, CA 92705

APR 15 2013

Re: P980040/S039
TECNIS® Toric 1-Piece Intraocular Lens (IOL), Models ZCT150, ZCT225, ZCT300, and ZCT400, and the TECNIS® Toric Calculator System
Filed: April 30, 2012
Amended: August 1, August 24, November 1 and November 8, 2012
Procode: MJP

Dear Dr. Yetemian:

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 TECNIS® Toric 1-Piece IOL, Models ZCT150, ZCT225, ZCT300 and ZCT400, and the TECNIS® Toric Calculator System. This device is indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder and increased spectacle independence for distance vision. The device 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 four (4) 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 must provide the following data in separate post-approval study (PAS) reports. As a condition of approval, you must conduct the following post-approval study:

The New Enrollment Post-Approval Study: Per your agreement via e-mail dated April 4, 2013, this study will evaluate the visual distortions for the TECNIS® Toric IOLs with ≥2.0 D of cylinder correction at the corneal plane (Models ZCT300 and ZCT400). This study will be in a larger population, in clinical practice, compared to a control and is meant to ensure the continued safety of the approved devices. This study will be conducted in two phases:

a. Validation Phase: Before beginning patient enrollment in the PAS phase, you will conduct a validation study of the patient reported outcomes (PRO) instrument, including qualitative and quantitative validation, as outlined in the file "PRO INSTRUMENT VALIDATION FOR THE POST-APPROVAL STUDY OF THE TECNIS TORIC LENS MODELS, ZCT300 AND ZCT400, PROTOCOL NUMBER: TIOL-201-VPAS" included in your email dated April 4, 2013. Results of the complete validation of the PRO instrument will be provided within 9 months. The PRO instrument will need to be approved by FDA before it can be used in the PAS phase.

b. PAS Phase: This phase will consist of a prospective, multicenter (up to 80 sites), bilateral, non-randomized, open-label comparative clinical study of TECNIS® Toric patients implanted with ZCT300 and/or ZCT400 IOLs compared to monofocal patients with the same level of preoperative corneal astigmatism.

   The primary endpoint consists of the rates of severe complications related to visual distortions at 6 months for the following items: 1) things appearing distorted; 2) objects appearing tilted; 3) floors or flat surfaces appearing curved; and 4) queasiness related to vision. Rates of severe complications related to visual distortions for the TECNIS® Toric IOL group will be no greater than 10 percentage points above those for the monofocal control group.

A total of 385 patients will be enrolled: 220 TECNIS® Toric ZCT300 and ZCT400 patients and 165 control patients, assuming a 10% drop-out rate, a minimum of 200 Toric and 150 control patients will be available for evaluation at 6 months.

The complete adverse event (AE) data will also be reported. This includes the comparative incidence and severity of AEs by treatment group, comparison of device-related events and comparison of unanticipated AEs.

Please be advised that the results from these studies 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.

Within 30 days of your receipt of this letter, you must submit PMA supplements that include complete protocols of the validation study and the post-approval study. Your PMA supplements should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the PMA Supplement number above to facilitate processing. 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.

FDA would like to remind you that you are asked to submit separate PAS Progress Reports every six months during the first two years of the study. The reports should clearly be identified as Post-Approval Study Report. Two copies for each study, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. 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 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 six 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 Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Claudine Krawczyk at (301) 796-6860.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health