July 22, 2022

AcuFocus, Inc.
Magda Michna, Ph.D.
Chief Global Clinical, Medical and Regulatory Affairs Officer
32 Discovery, Suite 200
Irvine, CA 92618

Re: P210005
Trade/Device Name: IC-8® Apthera™ Intraocular Lens (IOL)
Product Code: POE
Filed: February 24, 2021
Amended: September 22, 2021

Dear Dr. Michna:

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 IC-8® Apthera™ Intraocular Lens (IOL). The IC-8® Apthera™ IOL is indicated for unilateral implantation for the visual correction of aphakia and to create monovision in patients of age 22 or older who have been diagnosed with bilateral operable cataract, who have up to 1.5 D of astigmatism in the implanted eye, and who do not have a history of retinal disease and who are not predisposed to experiencing retinal disease in the future. The device is intended for primary implantation in the capsular bag, in the non-dominant eye, after the fellow eye has already undergone successful implantation (uncorrected distance visual acuity 20/32 or better and best-corrected distance visual acuity 20/25 or better) of a monofocal or monofocal toric IOL that is targeted for emmetropia. The refractive target for the IC-8® Apthera™ IOL should be -0.75 D. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal or monofocal toric IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. 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. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

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 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 6 months with a storage temperature between 41° F and 104° F (5° C to 40° C). 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. 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.

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.

You must obtain approval of your PAS protocol(s) within 60 days from the date of this order. Within 30 days of your receipt of this letter, you must submit PMA supplements that include complete protocols of your post-approval studies described below. Your PMA supplements should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted 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.

1. Post-Approval Study—Continuation Study “SAIL-101-PAS (continuation of IDE study G180075).” This study will be conducted as per the protocol outline in our November 16, 2021 email. On November 17, 2021, you agreed to conduct a study as follows:

   The continuation study, previously conducted per protocol SAIL-101-UNI approved under IDE G180075, is a prospective, single-arm, multi-center observational study. All available subjects from the IDE study who were successfully implanted with the IC-8® Apthera™ IOL in one eye and a monofocal or monofocal toric IOL in the fellow eye will be eligible to enroll in the continuation study. Subjects will be followed 3 years postoperatively. The study is designed to evaluate the long-term safety of the IC-8® Apthera™ IOL. All 343 IC-8® Apthera™ IOL subjects from the IDE study are intended to be re-consented at 21 sites, to ensure at least 300 subjects with 3-year data post-implantation are available for analysis.

   Data on the 2-year assessments will be obtained from medical records. The final scheduled follow-up visit will be at 3-years post-IOL implantation.

The primary safety endpoints are:

- Rates of Secondary Surgical Interventions (SSI), by type of SSI)
- Rate of eyes with other types of serious adverse events using analyses in ISO 11979-7 historical grid Table E.2-Posterior chamber IOL adverse events
- Rate of subjective visual disturbances

Descriptive statistics will be used to analyze the primary and secondary safety endpoints related to cumulative adverse event rates, including analysis of the two-sided 95% Confidence Intervals.

From the time of study protocol approval, you must meet the following timelines for the reconsent process:

- First subject enrolled within 4 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 15 months
- 100% of subjects enrolled within 18 months
- Submission of Final study report: 3 months from study completion (i.e. last subject, last follow-up date)

2. Post-Approval Study—New Enrollment Study "IC-8 Apthera IOL New Enrollment Post Approval Study." This study will be conducted as per the protocol outlined in our November 16, 2021 email. On November 17, 2021, you agreed to conduct a study as follows:

   This study will be conducted in two phases:

   Phase A: Surgeon-Training Program. Before starting enrollment for Phase B of the PAS, you will perform non-interventional, qualitative research to create a clinician-focused training program for the treatment of Posterior Capsular Opacity (PCO), an expected complication related to IC-8® Apthera™ IOL implantation. The objective of Phase A is to develop a clinician-focused training program that ensures proper training for the treatment of PCO.

   Phase B: New Enrollment. This Phase will begin after development of the surgical training plan in Phase A is completed and has been accepted by FDA. The objective of Phase B will be to verify the safety of the IC-8® Apthera™ IOL after the treatment of PCO.

   Phase B is a prospective, multi-center, single-group, non-randomized new enrollment post-approval study to assess post-market safety of the IC-8® Apthera™ IOL. The study objective is to verify the post-market safety of the IC-8® Apthera™ IOL after the treatment of PCO, an expected complication related to IC-8® Apthera™ IOL implantation.

   The study population will include subjects implanted with the IC-8® Apthera™ IOL in accordance with the Directions for Use. Subjects enrolled will be those that have developed PCO following IC-8® Apthera™ IOL implantation that requires treatment of posterior capsular opacification.
   Sample size calculations are based on a desired precision around the point estimate for the explant rate. Assuming an explant rate of 0.5%, a 95% exact (Clopper-Pearson) upper confidence limit with precision

of 1.0% (i.e., an upper CL of 1.5%) would require 435 subjects. Taking into account 10% attrition rate over 24 months, the study should enroll 483 subjects that have developed PCO and require treatment to ensure a minimum of 435 subjects with follow-up through the course of the study.

Subjects will be enrolled and followed up to 24-months post IC-8® Apthera™ IOL implantation. The scheduled visits for all subjects will include: PCO treatment visit (including assessments prior to PCO treatment procedure), 1-week post PCO treatment visit, 1-month post PCO treatment visit, 12-months and 24-months post IC-8® Apthera™ IOL implantation visits. If visit windows align, the 1-week and 1-month post PCO treatment visits may be combined with the 12-months and 24-months post IC-8® Apthera™ IOL implantation visits. Non-directed questions pertaining to subjective visual symptoms will be asked at the 1-week and 1-month post PCO treatment visit as well as the 12-months and 24 months post IC-8® Apthera™ IOL implantation visits. Patient reported outcomes (PROs) will be assessed for all subjects at each of the following scheduled visits: PCO treatment visit (pretreatment), 1-month post-PCO treatment, 12-months post-IC-8® Apthera™ implantation, and 24-months post-IC-8® Apthera™ implantation, using the Quality of Vision (QoV) instrument (McAlinden 2010) and the (revised) Small Aperture Patient Questionnaire (SAPQ).

The co-primary safety endpoints and/or parameters include the following: the rates of YAG (including the rate of initial YAG, and the rate of any additional YAG treatments beyond the initial YAG treatment), YAG outcome and/or complications, IOL-related assessments (including mask appearance and indication of any YAG damage), rates of secondary surgical interventions (pars plana vitrectomy, explant, etc.), other serious ocular adverse events (as described in ISO 11979-7 historical grid), and rates of subjective visual disturbance.

Other parameters that will be collected in the study include but are not limited to the following: YAG laser technique details and/or settings, YAG difficulty; best-corrected distance visual acuity; uncorrected visual acuities. Patient-reported outcomes (PROs) will be assessed with the Quality of Vision (QoV) instrument (McAlinden 2010) and the (revised) Small Aperture Patient Questionnaire (SAPQ); the SAPQ will be based on the original version used in the IC-8® Apthera™ IOL IDE study and will be revised to include two additional items assessing the concepts of “vision differences between two eyes” and “floaters”.

There is no formal study hypothesis; descriptive data on the long-term performance of the IC-8® Apthera™ IOL will be collected. The study will provide point estimates with two-sided 95% CI for the study endpoints. Descriptive statistics will be reported on the data collected in this study, including but not limited to the following: sample size (N), mean, standard deviation (SD), median, minimum (Min), and maximum (Max) and 95% confidence interval as applicable for continuous variables, and sample size (N), frequency and percent of relevant total (rate) and two-sided 95% confidence interval (or one-sided 97.5% confidence limit) as applicable for categorical and some ordinal variables.

From the time of study protocol approval, you must meet the following timelines for the New Enrollment Study:

- Submit the surgical training plan for Phase A for FDA acceptance within 1 month.
- After receiving FDA acceptance of Phase A surgical training plan, successfully complete the Phase A surgical training plan for 100% of participating Investigators within 6 months.

- The enrollment of subjects that have developed PCO following IC-8® Apthera™ IOL implantation that requires treatment of posterior capsular opacification (Phase B) will begin following the successful training of the first Investigator in Phase A. An Investigator must be trained prior to enrolling their first subject. The subject enrollment milestones for Phase B are as follows:

    - First subject enrolled within 6 months
    - 20% subjects enrolled within 12 months
    - 50% subjects enrolled within 18 months
    - 100% subjects enrolled within 24 months
    - Submission of Final study report: 3 months from study completion (i.e., last subject, last follow-up date)

In addition, you must submit separate periodic reports on the progress of the New Enrollment Study as follows:

- PAS Progress Reports every six (6) months for the first two years of the study and annually thereafter.
- There will be two interim data release postings, as follows: summary descriptive statistics on the adverse events will be posted when 20% and 50% of enrolled subjects reach the last follow-up assessment (24-months). All safety endpoints will be evaluated and posted on the FDA PAS website as required.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports (i.e., every 3 months), in addition to your periodic (6-months) PAS Progress Reports, until FDA notifies you otherwise.

For the Continuation Study, you must submit separate PAS Progress Reports every six (6) months through the completion of the study. There will be interim results posted with summary statistics on the study endpoints, when 2-year data is available for all subjects.

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including the initiation, enrollment, and completion requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

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 accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

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" (https://www.fda.gov/media/71327/download).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (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. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

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" https://www.fda.gov/media/81431/download.

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 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, 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 https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

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 Home Page located at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. 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 a copy 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, 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
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 Oliver Flynn, Ph.D. at 301-837-7437 or Oliver.Flynn@fda.hhs.gov.

Sincerely,

Kesia Alexander

for Tieuvi Nguyen, Ph.D.
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health