



September 13, 2018

STAAR Surgical Company
Ms. McEachern
Global Head of Regulatory Affairs/Quality Assurance
1911 Walker Ave
Monrovia, CA 91016

Re: P030016/S001
Trade/Device Name: Visian[®] Toric ICL (Implantable Collamer[®] Lens)

Dear Ms. McEachern:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its review of your premarket approval application (PMA) Supplement and issued an approval order on September 13, 2018. We inadvertently made an error in the indications for use statement (IFU) within your approval order. The correct IFU should read as follows:

This device is indicated for use in patients 21-45 years of age:

1. for the correction of myopic astigmatism with spherical equivalent ranging from -3.0D to \leq -15.0D (in the spectacle plane) with cylinder (spectacle plane) of 1.0D to 4.0D.
2. for the reduction of myopic astigmatism with spherical equivalent ranging from greater than -15.0D to -20.0D (in the spectacle plane) with cylinder (spectacle plane) 1.0D to 4.0D.
3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5D for both spherical equivalent and cylinder for 1 year prior to implantation).
4. The Visian[®] TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

We hope that this error has not inconvenienced you. If you have any questions about this corrective action, please contact Tieuvi Nguyen at 301-796-7018 or Tieuvi.Nguyen@fda.hhs.gov.

Sincerely,

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



September 13, 2018

STAAR Surgical Company
Ms. Denise McEachern
Global Head of Regulatory Affairs/Quality Assurance
1911 Walker Ave
Monrovia, CA 91016

Re: P030016/S001

Trade/Device Name: Visian[®] Toric ICL (Implantable Collamer[®] Lens)

Filed: May 8, 2006

Amended: June 20, 2006, June 29, 2006, July 13, 2006, July 14, 2006, July 28, 2006,
August 7, 2006, January 16, 2007, May 11, 2007, June 12, 2007, October 21,
2008, November 6, 2008, August 2, 2010, March 1, 2012, May 18, 2012,
November 16, 2012, July 24, 2013, September 30, 2014, and June 1, 2017

Product Code: QCB

Dear Ms. McEachern:

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 Visian[®] Toric ICL (Implantable Collamer[®] Lens). This device is indicated for use in patients 21-45 years of age:

1. for the correction of myopic astigmatism in adults with spherical equivalent ranging from -3.0D to \leq -15.0D (in the spectacle plane) with cylinder (spectacle plane) of 1.0D to 4.0D.
2. for the reduction of myopic astigmatism in adults with spherical equivalent ranging from greater than -15.0D to -20.0D (in the spectacle plane) with cylinder (spectacle plane) 1.0D to 4.0D.
3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5D for both spherical equivalent and cylinder for 1 year prior to implantation).
4. The Visian TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

We are pleased to inform you that the PMA supplement is approved. You may continue commercial distribution of the device upon receipt of this letter.

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). 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 two 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. 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. 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. Each report, identified as a "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.

Visian® Toric ICL New Enrollment PAS: The Visian® Toric ICL New Enrollment PAS is a prospective, multicenter, open-label, single arm, new enrollment post-approval study, designed to evaluate the long-term safety and effectiveness of the Visian® Toric ICL. A total of 124 subjects (up to 248 eyes, with 124 being primary), will be enrolled at 6-8 clinical sites in the USA. One hundred (100) subjects (assuming an overall attrition of 10% per year) will be available for evaluation at 24 months after implantation. A minimum of 14 subjects requiring a Toric ICL cylinder power of 3.5 or 4.0 diopters will be enrolled.

Study subjects will be followed at Day 0, Day 1, Week 1, Month 1, 3, 6, 12, 18, and 24 postoperatively.

The primary study endpoint is to evaluate the long-term rotational stability as determined relative to objective landmarks on the eye. The performance goal is to detect if at least 90% of the treated eyes rotate less than or equal to five degrees between 18 and 24 months postoperative.

The secondary study endpoints include: Absolute rotation between visits, Absolute rotation <5 degrees, <10 degrees, <20 degrees, and <30 degrees from the intended orientation at each visit, Absolute rotation from the intended orientation at each visit, and Postoperative manifest refraction spherical equivalent and cylinder at each visit. The degrees of rotation between visits and misalignment from the intended orientation will be analyzed using descriptive statistics. Rates of rotation of the device of <10, <20 and <30 degrees from the intended orientation will be reported. Summaries for continuous variables will include the number of non-missing values, mean, standard deviation, median, minimum, and maximum. Summaries for discrete variables will include the tabulation of frequencies and percentages. Ocular adverse event (AE) rates assessed in implanted eyes will be estimated.

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 "PMA Post-Approval Study Protocol" as noted above 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.

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. 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, <http://www.fda.gov/udi>.

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 for devices or postmarketing 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> and on combination product postmarketing safety reporting is available at (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing 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 <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, 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 Tieuvi Nguyen, Ph.D. at 301-796-7018 or Tieuvi.Nguyen@fda.hhs.gov.

Sincerely,

Denise L. Hampton -S

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