March 25, 2022

STAAR Surgical Company
Denise McEachern
Global Head of Regulatory Affairs
1911 Walker Avenue
Monrovia, California 91016

Re: P030016/S035
Trade/Device Name: EVO/EVO+ VISIAN Implantable Collamer® Lens (EVO ICL™) and
EVO/EVO+ VISIAN TORIC Implantable Collamer® Lens (EVO TICL™)
Product Code: MTA, QCB
Filed: February 5, 2019
Amended: October 29, 2019; October 26, 2020; and April 22, 2021

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 EVO/EVO+VISIAN Implantable Collamer Lens. This device is indicated for

The EVO ICL is indicated for use in patients 21-45 years of age:
1. or the correction of myopia ranging from -3.0D to ≤ -15.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;
2. for the reduction of myopia ranging from greater than -15.0D to -20.0D with less than or equal to 2.5D of astigmatism at the spectacle plane;
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 1 year prior to implantation).
4. The ICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

The EVO TICL 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 ≤ -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 0.5 D for both spherical equivalent and cylinder for 1 year prior to implantation).
4. The 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 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). 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.

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. The CP19-01- Post Approval Follow-Up of PMA Cohort is a continuation of IDE study G190184. This study will be conducted as per the protocol outline in our March 16, 2022, email. On March 17, 2022, you agreed to conduct the continuation study, previously conducted per protocol CP19-01 approved under IDE G190184, which is a prospective, single-arm, multi-center, observational study. The study is

designed to evaluate the long-term safety and collect supportive data concerning the effectiveness of the EVO/EVO+ Visian Implantable Collamer Lens. All 327 available subjects enrolled and who completed postoperative Visit 5 under the original IDE study are intended to be reconsented at the 14 clinical sites to enroll in the continuation study. Subjects will continue follow-up at regular intervals as follows: postoperative visit 6 (330-420 days), postoperative visit 7 (690-810 days), and postoperative visit 8 (1050-1170 days) to ensure at least 300 eyes with 3-year data post-implantation are available for analysis.

The co-primary endpoints are:

- Distribution of percent endothelial cell density (ECD) losses and the percent of eyes that have ECD <1500 and ECD <1000 through Postoperative Visit 8 (Day 1050 – 1170).
- Incidence of adverse events (AEs) through Postoperative Visit 8 (Day 1050 – 1170).

Co-primary endpoints will be evaluated in all eyes (primary and fellow eyes) using descriptive statistics with comparisons to PMA data for the approved and currently marketed MICL and TMICL devices, where appropriate. The co-primary endpoints have no prespecified performance targets.

The following timelines for the continuation study will be met:

- Submit an annual report by August 23 of each year, beginning on August 22, 2022.
- Complete 36-month follow-up on all PAS subjects by August 23, 2024 (36 months)
- The Final study report will be submitted 3 months from study completion (i.e., last subject, last follow-up date).

2. The Post-Market Evaluation of the EVO ICL is a new enrollment, prospective, multi-center, single arm post-approval study. This study will be conducted as per the protocol outline in our March 16, 2022, email. On March 17, 2022, you agreed to conduct the new-enrollment study. The study is designed to evaluate the success of the EVO Physician Certification Program in reducing the rate of early IOP increases at 1-6 hours after implantation of EVO/EVO+ ICL lenses by surgeons who have been trained and certified under the EVO Physician Certification Program. The study will enroll at least 200 subjects. Subjects will continue follow-up for up to about two weeks post-implantation at the following timepoints: 1-6 hours postoperatively, 1 day postoperatively, 5-9 days postoperatively, and 10-18 days postoperatively. The primary endpoint is the proportion of primary eyes that have IOP ≥ 30 mmHg and IOP ≥ 40 mmHg at 1-6 hours postoperatively. The secondary endpoint is the proportion of fellow eyes that have IOP ≥ 30 mmHg and IOP ≥ 40 mmHg at 1-6 hours postoperatively.

From the time of study protocol approval, you must meet the following timelines for Post-Market Evaluation of the EVO ICL:

- First subject enrolled within 6 months from the time of protocol approval
- 20% of subjects enrolled within 12 months from the time of protocol approval
- 50% of subjects enrolled within 18 months from the time of protocol approval
- 100% of subjects enrolled within 24 months from the time of protocol approval

- 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 Post-Market Evaluation of the EVO ICL as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter.
- 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 all other condition of approval studies, you must submit separate PAS Progress Reports for each study, every six (6) months for the first two (years) and annually thereafter, unless otherwise specified by FDA.

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 Kaccie Y Li at 301-796-6171 or Yiang.Li@fda.hhs.gov.

Sincerely,

Tieuvi H. Nguyen -S

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

March 29, 2022

STAAR Surgical Company
Ms. Denise McEachern
Global Head of Regulatory Affairs
1911 Walker Avenue
Monrovia, California 91016

Re: P030016/S035
Trade/Device Name: EVO/EVO+ VISIAN Implantable Collamer® Lens (EVO ICL™) and EVO/EVO+ VISIAN TORIC Implantable Collamer® Lens (EVO TICL™)

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 March 25, 2022. We inadvertently made an error with the Indications for Use (IFU) language. The correct IFU is as follows:

The EVO ICL lens is indicated for use in patients 21-45 years of age:

1. for the correction of myopia with spherical equivalent ranging from -3.0 D to ≤ -15.0 D with less than or equal to 2.5 D of astigmatism at the spectacle plane;
2. for the reduction of myopia with spherical equivalent ranging from greater than -15.0 D to -20.0 D with less than or equal to 2.5 D of astigmatism at the spectacle plane;
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 0.5 D for 1 year prior to implantation).
4. The ICL lens is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

The EVO TICL lens is indicated for use in patients 21-45 years of age:

1. for the correction of myopic astigmatism with spherical equivalent ranging from -3.0 D to ≤ -15.0 D (in the spectacle plane) with cylinder (spectacle plane) of 1.0 D to 4.0 D.
2. for the reduction of myopic astigmatism with spherical equivalent ranging from greater than -15.0 D to -20.0 D (in the spectacle plane) with cylinder (spectacle plane) 1.0 D to 4.0 D.
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 0.5 D for both spherical equivalent and cylinder for 1 year prior to implantation).
4. The TICL lens 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 Yiang Li at 301-796-6171 or Yiang.Li@fda.hhs.gov.

Sincerely,

Tieuvi H. Nguyen -S

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