September 25, 2025

Essilor of America, Inc.
John Anderson
Sr. Director of Compliance
13455 Branchview Lane
Dallas, TX 75234

Re: DEN250016
Trade/Device Name: Essilor® Stellest®
Regulation Number: 21 CFR 886.5845
Regulation Name: Prescription spectacle lenses to reduce the progression of myopia
Regulatory Class: Class II
Product Code: QUR
Dated: April 28, 2025
Received: April 28, 2025

Dear John Anderson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Essilor® Stellest®, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Essilor® Stellest® lens is indicated for the correction of myopia with and without astigmatism and for slowing the progression of myopia in children with non-diseased eyes, who, at initiation of treatment, are aged 6-12 years and have spherical equivalent refraction of -0.75 D to -4.50 D with astigmatism up to 1.50 D.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Essilor® Stellest®, and substantially equivalent devices of this generic type, into Class II under the generic name prescription spectacle lenses to reduce the progression of myopia.

FDA identifies this generic type of device as:

> **Prescription spectacle lenses to reduce the progression of myopia**. Prescription spectacle lenses to reduce the progression of myopia consist of spectacle lenses with additional physical optical design lens elements. In addition to optical correction of myopic refractive error, these lenses are intended to be used by patients who have myopia to reduce the rate of myopia progression. The lenses are mounted within a spectacle frame classified under § 886.5842.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act.
On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 28, 2025, FDA received your De Novo requesting classification of the Essilor® Stellest®. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Essilor® Stellest® into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Essilor® Stellest® can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Failure to slow the progression of myopia, leading to poorer long-term vision and increased risk of myopia-related ocular disease	Clinical performance testing Postmarket surveillance Non-clinical performance testing Labeling
Adverse visual symptoms or impaired visual performance	Clinical performance testing Labeling
Lens breakage leading to eye injury	Non-clinical performance testing

In combination with the general controls of the FD&C Act, the prescription spectacle lenses to reduce the progression of myopia is subject to the following special controls:

(1) Data obtained from premarket clinical performance validation testing, and from postmarket surveillance conducted per a protocol approved by FDA and acquired under anticipated conditions of use, must demonstrate that the device performs as intended when used in the intended patient population, and must evaluate the following, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required:
    (i) Assessment of the change in spherical equivalent refractive error and axial length in the intended patient population as compared to a clinically justified control group. Data must demonstrate the following:
        (A) The lower bound of the 95% confidence interval for the difference in mean refractive error as compared to the control is no less than -0.50 diopters spherical equivalent with a

corresponding change in axial length as compared to control. If these endpoints are not achieved, an alternative clinical justification must be provided; and

(B) Clinical performance testing must demonstrate that the device has a continuing cumulative treatment effect in both spherical equivalent refraction and axial length over the duration of the study;

(ii) Assessment of adverse events and visual symptoms, considering the specific design characteristics of the device;

(iii) Assessment of rebound effect after cessation of device use; and

(iv) Assessment of the impact of optical lens design elements on visual performance (e.g., visual acuity and contrast sensitivity) and vision-related activities (e.g., reading and peripheral vision).

(2) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following testing must be provided:

(i) Impact resistance testing requirements as required by 21 CFR 801.410;

(ii) Optical and bench testing of the critical parameters, including:

(A) Optical characterization testing;

(B) Durability testing; and

(C) Performance testing to verify technical specifications.

(3) Labeling for the healthcare professional; and labeling for the patient and/or caregiver that accompanies the device to be dispensed, must include the following:

(i) A description of the optical design elements;

(ii) The recommended wearing schedule;

(iii) For patient and/or caregiver labeling, fitting considerations from the patient and/or caregiver perspective;

(iv) For healthcare professional labeling, instructions for fitting and positioning of the lenses in the frame relative to the primary gaze position;

(v) A description of what lens tint(s) or coating(s) were used in clinical testing and a warning that the effectiveness of the lenses was not studied with other coating(s) or tint(s);

(vi) A summary of the visual and clinical performance testing obtained with the device; and

(vii) A detailed summary of relevant postmarket surveillance data collected, including updated labeling to accurately reflect outcomes observed in postmarket surveillance.

In order to satisfy special control (1)(iii) above, FDA has determined that you must conduct postmarket surveillance as outlined below. FDA has determined that you must collect and report postmarket surveillance data acquired under anticipated conditions of use to assess for the presence of a rebound effect after cessation of device use in the intended patient population. Specifically, you must conduct a postmarket clinical validation performance testing of the Essilor® Stellest® device in the intended patient population to determine if there is an increase in myopia progression after discontinuing device use as compared to a control group wearing single-vision spectacle lenses.

FDA expects that the postmarket clinical validation performance testing will recruit subjects who completed the effectiveness study (FIN-3101 study). The study will characterize the change in axial length and spherical equivalent refractive error experienced by subjects 12 months after cessation of treatment with the device, as compared to a control group wearing single vision spectacle lenses. You will also collect data on all observed ocular adverse events. Follow-up visits will occur at 6 and 12 months.

The co-primary endpoints will be the magnitude of change in the spherical equivalent refractive error and axial length from baseline.

Within 30 days of receipt of this order, you must submit a complete study protocol for your study as described above. FDA expects to work with you to approve you study protocol within 60 days of this order. Your submission should be clearly labeled as a "Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the De Novo number above to facilitate processing. If there are multiple protocols being finalized after granting of this De Novo request, please submit each protocol as a separate submission, identified by their unique study name(s).

From the date of study protocol approval, you must meet the following timelines:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

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

- Postmarket surveillance progress reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the protocol approval letter, unless otherwise specified by FDA.

- If any enrollment milestones are not met, you must begin submitting enrollment status reports every three (3) months, in addition to your periodic postmarket study progress reports, until enrollment has been completed, or FDA notifies you otherwise.

- Submit the final postmarket study report three (3) months from study completion (i.e., last subject's last follow-up date).

Each postmarket surveillance report should be submitted to the Agency as specified below, identified as "Postmarket Surveillance Report" in accordance with how the study is identified above, and bearing the applicable De Novo reference number.

Be advised that failure to comply with any special control requirement, including the initiation, enrollment, completion, and reporting per the postmarket surveillance data requirements outlined above, may result in the adulteration and misbranding of your device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the prescription spectacle lenses to reduce the progression of myopia they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above De Novo number to facilitate processing.

Postmarket Mandated Studies Program
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

Alternatively, documents can be submitted electronically through the CDRH Portal. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any questions concerning the contents of the letter, please contact Elissa Wong at 240-402-0204.

Sincerely,

Denise L. Hampton -S

for Kesia Alexander, Ph.D.
Director (Acting)
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health