DE NOVO CLASSIFICATION REQUEST FOR ESSILOR® STELLEST®

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 886.5845

CLASSIFICATION: Class II

PRODUCT CODE: QUR

BACKGROUND

DEVICE NAME: Essilor® Stellest®

SUBMISSION NUMBER: DEN250016

DATE DE NOVO RECEIVED: April 28, 2025

SPONSOR INFORMATION:

Essilor of America, Inc.
13455 Branchview Lane
Dallas, Texas 75234

INDICATIONS FOR USE

The Essilor® Stellest® is indicated as follows:

> 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 the 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.

LIMITATIONS

The sale, distribution, and use of the Essilor® Stellest® spectacle lens is restricted to prescription use in accordance with 21 CFR 801.109.

The following warnings and precautions apply to the Essilor® Stellest® spectacle lenses:

Warnings:
As spectacles are manufactured based on a precise prescription, the eye care professional should ensure they are correctly fitted and appropriately assessed on the patient.

The Essilor® Stellest® spectacle lens, like any ophthalmic lens, may require an initial adaptation period, typically under one week. During this period, it is advisable to avoid high-impact activities where altered vision could present a risk. If adaptation takes longer or causes significant issues, it is recommended the wearer consults their eye care professional.

The lenses used in the FIN-3101 clinical trial were equipped with a Crizal Easy Pro coating, which does not provide any tint or filtering capabilities.

Patients should be advised of the following warnings pertaining to Essilor® Stellest® spectacle lenses:

- *The effectiveness of the lens to slow myopia progression was not studied with any tints or filters. Speak to your doctor before adding any tint or filters to the lenses, as it is possible these may impact device effectiveness.*

Precautions:
At this point, potential rebound effects (i.e., accelerated myopia progression following discontinuation of Essilor® Stellest® spectacle lens wear compared to single vision lenses) have not been evaluated in U.S. patients.
The effects of Essilor® Stellest® spectacle lenses on reading skill development and on peripheral visual function—including obstacle detection in the periphery—are unknown.

DEVICE DESCRIPTION

The Essilor® Stellest® is a prescription only (Rx only) device that is a pair of spectacle lenses fitted with the patient's refractive prescription. The unique features of this device are concentric rings of aspheric lenslets (small lenses) which focus portions of the incoming light in front of the retina, causing blur on the retina. The figure below shows a single lens where the 9mm diameter central zone is free from lenslets and 11 concentric lenslet rings are visible. Each ring has a slightly different focusing power. The device is designed to slow the elongation of the eye and a provide a reduction in the progression of myopia in myopic children.

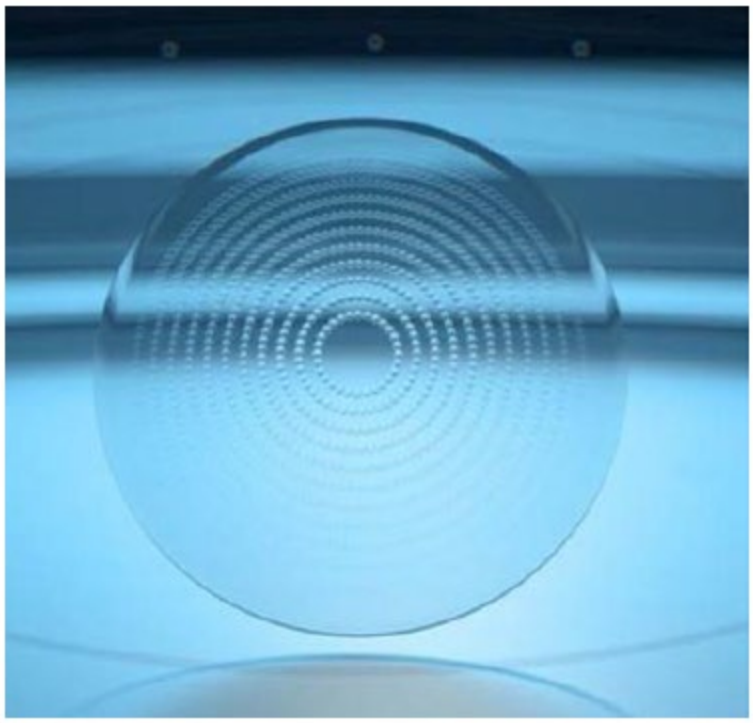

Figure 1: A single Essilor® Stellest® spectacle lens is pictured above, showing where the central zone is free from lenslets and 11 concentric lenslet rings are visible.

The Essilor® Stellest® spectacle lenses are intended to be worn by a pediatric patient in a spectacle frame, as eyeglasses are worn. There is no specific frame that comes with the Essilor® Stellest® lenses. Rather, the Essilor® Stellest® lenses are mounted into a chosen spectacle frame, based on patient preference in conjunction with their healthcare provider or optician. The Essilor® Stellest® lenses are made from polycarbonate with Crizal® Easy Pro coating, an anti-reflectance coating, and are not tinted. Labeling for the Essilor® Stellest® device is provided to both the healthcare provider/optician and the pediatric patient/caregiver(s).

One example of Essilor® Stellest® spectacle lenses, mounted into a spectacle frame as eyeglasses are, is shown below.

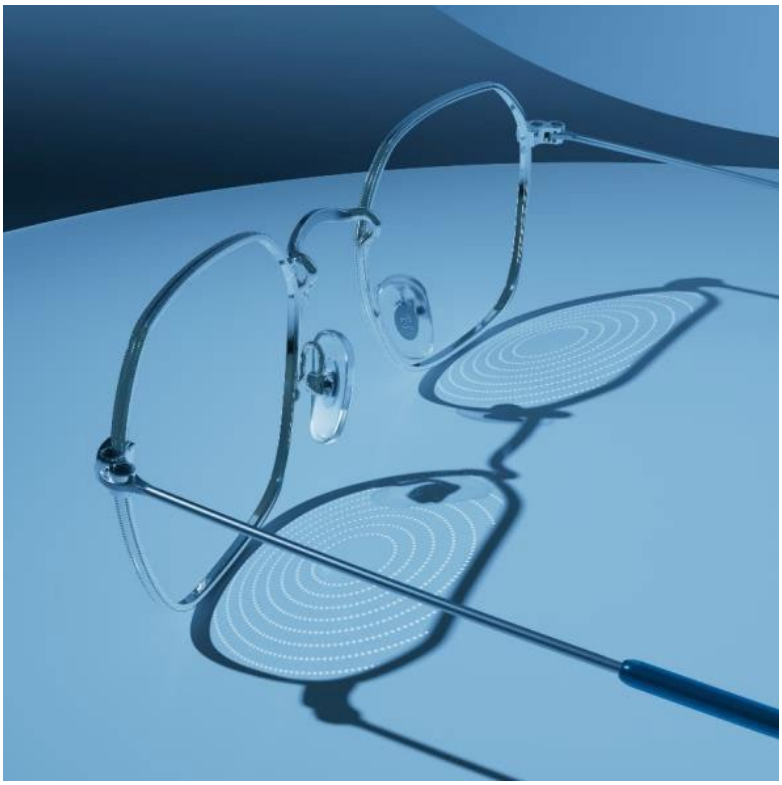

Figure 2: Photograph of an example spectacle frame (eyeglasses) that contain Essilor® Stellest® spectacle lenses

SUMMARY OF NONCLINICAL/BENCH STUDIES

PERFORMANCE TESTING - BENCH

Non-clinical testing for the Essilor® Stellest® spectacle lenses included the following:

- Optical power
- Spectral transmittance
- Adhesion/reflectance testing
- Abrasion testing
- Prescription Ophthalmic Lenses Recommendations
- Requirements for uncut finished lenses
- Impact resistance testing
- Aging simulation test
- Lenslet dimensional testing
- Lenslet power testing
- Spectral transmittance
- Lenslet dimensional testing
- Lenslet power testing
- Abrasion testing

- Adhesion/reflectance testing
- Impact resistance testing
- Prescription Ophthalmic Lenses Recommendations
- Requirements for uncut finished lenses
- Aging simulation test
- Wearer simulation at the hands of the wearer

Table 1 below provides a detailed summary of the non-clinical bench and optical testing performed for the Essilor® Stellest® spectacle lenses.

PERFORMANCE TESTING - BENCH

Table 1: Summary of Performance Testing – Bench Studies

Test	Purpose	Method	Acceptance Criteria	Results
Optical Power	Verify that the device meets the ISO 8980-1 specifications.	Based on ISO 8980-1: Ophthalmic optics – Uncut finished spectacle lenses – Part 1: Specifications for single-vision and multifocal lenses	ISO 8980-1:2017: Ophthalmic optics – Uncut finished spectacle lenses – Part 1: Specifications for single-vision and multifocal lenses	Passed
Spectral Transmittance	Evaluate the spectral transmittance of the device.	Based on ISO 8980-3 : 2022 Ophthalmic optics — Uncut finished spectacle lenses — Part 3: Transmittance specifications and test methods.	ISO 8980-3 : 2022 Ophthalmic optics — Uncut finished spectacle lenses — Part 3: Transmittance specifications and test methods.	Passed
Adhesion/ Reflectance	Evaluate the device for reflectance and adhesion	Based on ISO 8980-4 : 2006 Ophthalmic optics — Uncut finished spectacle lenses — Specifications and test methods for anti-reflective coatings	ISO 8980-4 : 2006 Ophthalmic optics — Uncut finished spectacle lenses — Specifications and test methods for anti-reflective coatings	Passed
Abrasion	Evaluate the resistance of the lens surface to abrasion damage during normal use	Based on ISO 8980-5 : 2005 Ophthalmic optics — Uncut finished spectacle lenses - Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant	ISO 8980-5 : 2005 Ophthalmic optics — Uncut finished spectacle lenses — Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant	Passed
Prescription Ophthalmic Lenses Recommendations	Verify that the device conforms to the ANSI Z80-1.	Based on ANSI Z80-1: 2020 - for Ophthalmics – Prescription	ANSI Z80-1: 2020 - for Ophthalmics – Prescription	Passed

		Ophthalmic Lenses – Recommendations	Ophthalmic Lenses – Recommendations	
Requirements for uncut finished lenses	Verify that the device meets the requirements for uncut lenses	Based on ISO 14889:2013 Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses	ISO 14889:2013 Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses	Passed
Impact Resistance	Verify the ability of the device not to break and injure patient eye and/or skin when put under standard usage impact	Based on 21 CFR 801.410	21 CFR 801.410	Passed
Lenslet dimensional testing	Verify that the lenslets rings are the correct size and contain the correct number of lenslets	Optical testing performed by deflectometry was conducted where the lens is located between a screen and a camera. A sinusoidal grid pattern is displayed on the screen. The image of this pattern through the lens is acquired by the camera and processed to provide power and geometrical measurements.	Each ring has the correct number of lenslets and the distance from the center of the optic to each lenslet is within ±0.3 mm of the specification for that ring.	Passed
Lenslet power testing	Verify that the lenslet optical performance is as specified	Optical testing performed by deflectometry was conducted where the lens is located between a screen and a camera. A sinusoidal grid pattern is displayed on the screen. The image of this pattern through the lens is acquired by the camera and processed to provide power and geometrical measurements.	Average lenslet power around ring was within -0.5/+1.0 D of specification; Standard deviation around ring was ±0.25 D; max-min power within a ring was ≤ 0.65 D for rings 1-8 and ≤ 0.75 D for rings 9-11	Passed
Aging simulation test	Evaluate optics of the micro-lens and lens of the finished lens, Anti-reflective (AR) adhesion, AR transmittance, and impact resistance after simulated 3 years of storage of uncut lens	Optics of the finished lens: ISO 8980-1 Optics of the lenslet: See “Lenslet power testing” row above. Lenslet design: See “Lenslet dimensional testing” row above.	Optics of the finished lens: ISO 8980-1 Optics of the lenslet: See “Lenslet power testing” row above. Lenslet design: See “Lenslet dimensional testing” row above.	Passed

	prior to fabricating the finished product (glasses)	AR adhesion and transmittance: ISO 8980-4 Impact resistance: 21 CFR 801.410	AR adhesion and transmittance: ISO 8980-4 Impact resistance: 21 CFR 801.410	
Wearer simulation at the hands of the wearer	Evaluate the optical power of the lens and lenslets of the finished lens after simulated 2 years of wear.	Optical power of the lens and lenslets after Q-Sun exposure. Lens optical power: focimeter. Lenslet optical power: See "Lenslet power testing" row above.	Optical power of the lens: ISO 8980-1 and Z80.1 Optical power of the lenslet: See "Lenslet power testing" row above.	Passed

BIOCOMPATIBILITY

The Essilor® Stellest® spectacle lenses have no tissue contact when worn, as they are mounted within spectacle frames and are worn as eyeglasses. Spectacle frames used with Essilor® Stellest® lenses are class I (510(k) exempt) under 21 CFR 886.5842, product code HQZ. Because the lenses themselves have no tissue contact with the patient when worn and no additional biocompatibility evaluation is needed for class I spectacle frames, biocompatibility testing was not needed to support the safety of the subject device.

However, cytotoxicity testing per ISO 10993-5:2009 was performed on the Essilor® Stellest® spectacle lenses. Results support that the Essilor® Stellest® lenses were not cytotoxic.

SUMMARY OF CLINICAL INFORMATION

There were two studies conducted to evaluate the safety and effectiveness of the Essilor® Stellest® spectacle lenses. The FIN-3101 study evaluated the safety and effectiveness of the device as compared to a single vision control lens. The FIN-3102 study, a sub-study of the FIN-3101 study, evaluated visual performance through a variety of clinical tests and evaluations. An assessment was also provided that assessed the potential for rebound (an increase in myopia progression after discontinuing treatment) based on currently available information for the device.

FIN-3101 Clinical Study:

Overview:

Clinical performance data were collected from a pivotal clinical study (the FIN-3101 study).

The FIN-3101 study was a multicenter, randomized, controlled, prospective, two-arm, parallel-group, double-masked clinical trial. The study was conducted at 9 investigational sites in the U.S. The primary objective was to evaluate the effectiveness of the Essilor® Stellest® spectacle lens in slowing myopia progression compared to single vision control lenses. The study enrolled

175 participants between the ages of 6-12 years at initial fitting. Participants were consented for up to 3 years.

Key inclusion criteria included the following:

- Participants between 6 and 12 years of age;
- spherical equivalent refraction by manifest refraction between -0.75 and -4.50 diopters in each eye;
- astigmatism, if present, not exceeding 1.50 diopters;
- the difference in spherical equivalent refraction between the two eyes (anisometropia) by manifest refraction not exceeding 1.00 diopter;
- best corrected visual acuity in each eye equal to or better than +0.10 logMAR (equivalent to 20/25 Snellen).

Key exclusion criteria included the following:

- any history of myopia control interventions such as atropine, orthokeratology, or multifocal contact lenses;
- strabismus by cover test at near or distance while wearing correction;
- amblyopia;
- any ocular or systemic condition known to affect refractive status;
- current use of systemic or topical medications known to significantly affect pupil size, accommodation, or refractive state;
- current or anticipated use of growth hormones.

The FIN-3101 study participants were randomized equally between test and control groups. The study was conducted across nine investigational sites located throughout the United States, with each site recruiting between 7 and 28 subjects. The study enrolled 175 subjects, of whom 159 were randomized to test (77) and control (82) groups. Of the 175 subjects, 149 were dispensed study lenses. Of the 149 dispensed subjects, 91% (135/149) completed the 24-month visit, with completion rates of 93% (69/74) for the test group and 88% (66/75) for the control group. The dispensed population consisted of 52.3% males and 47.7% females, with a mean age of 10.2 years at baseline (range: 6.6 to 12.97 years). The largest racial group was White (63.8%), followed by East/Southeast Asian (20.1%) and Black/African-American (19.5%), with Hispanic or Latino ethnicity representing 22.8% of participants (see Table 2).

Table 2: Participant Demographics - Participants dispensed study lenses.

Variable		Total	Test	Control
No. of Subjects		149	74	75
Participant Integer Age (n(%))	6 yrs old	4 (2.7)	2 (2.7)	2 (2.7)
	7 yrs old	10 (6.7)	6 (8.1)	4 (5.3)
	8 yrs old	19 (12.8)	8 (10.8)	11 (14.7)
	9 yrs old	30 (20.1)	16 (21.6)	14 (18.7)

Variable		Total	Test	Control
	10 yrs old	35 (23.5)	16 (21.6)	19 (25.3)
	11 yrs old	35 (23.5)	16 (21.6)	19 (25.3)
	12 yrs old	16 (10.7)	10 (13.5)	6 (8.0)
	Mean (SD)	9.7 (1.52)	9.7 (1.59)	9.7 (1.47)
Sex (n(%))	Male	78 (52.3)	34 (45.9)	44 (58.7)
	Female	71 (47.7)	40 (54.1)	31 (41.3)
Ethnicity (n(%))	Hispanic or Latino	34 (22.8)	18 (24.3)	16 (21.3)
	Not Hispanic	115 (77.2)	56 (75.7)	59 (78.7)
Race* (n(%))	White	95 (63.8)	46 (62.2)	49 (65.3)
	East/Southeast Asian	30 (20.1)	14 (18.9)	16 (21.3)
	Black/African American	29 (19.5)	14 (18.9)	15 (20.0)
	South Asian	4 (2.7)	2 (2.7)	2 (2.7)
	American Indian or Alaska Native	2 (1.3)	0 (0)	2 (2.7)
	Native Hawaiian or Other Pacific Islander	1 (0.7)	1 (1.4)	0 (0)

* Proportions do not sum to 100% as subjects selecting more than one race will be counted multiple times.

The co-primary effectiveness endpoints were the change in spherical equivalent refraction from baseline, as measured by cycloplegic auto refraction, and axial length change from baseline. The pre-specified hypotheses for the primary co-effectiveness endpoints were that the changes in cycloplegic spherical equivalent refraction (SER) and axial length from baseline are significantly less with the Essilor® Stellest® lens compared with a single vision lens. The protocol pre-specified the evaluation of the co-primary effectiveness endpoints at 36 months, with a planned analysis at 24 months. The final analysis was based on the 24-month data.

Safety outcomes assessed included adverse events, best-corrected visual acuity (BCVA), and patient reported symptoms, problems, and complaints.

Clinical study results:

Effectiveness Outcomes

The FIN-3101 study demonstrated acceptable effectiveness of the Essilor® Stellest® spectacle lens in slowing myopia progression compared to single vision control lenses. For spherical equivalent refraction (SER), the study showed a 71% reduction in myopia progression at 24 months, with a calculated difference of 0.64 D (95% CI: 0.50 to 0.79 D) between test and control groups based on the Mixed effect model. For axial length, the test group showed a 53% reduction in axial elongation at 24 months, with a model-calculated difference of -0.24 mm (95% CI: -0.29 to -0.19 mm) compared to controls. Additionally, 56% of test eyes showed less than 0.25 D of myopia progression at 24 months compared to 19% of control eyes. The least-squares-

mean cycloplegic refractive error and axial length changeover 2-years are shown below in **Table 3**.

Table 3: Cycloplegic refractive error and axial length change over 2 years in the FIN-3101 randomized, controlled clinical trial. Difference calculated as Test minus Control. (LS Mean - multiple imputation – Intent-To-Treat (ITT) (159 subjects))

	Arm	LS Mean (SE)	95% CI	Difference in LS Means (SE)	95% CI of Difference	P-value	% Control
cSER	Essilor® Stellest®	-0.25 D (0.05)	-0.35 to -0.16	0.64 (0.07)	0.50 to 0.79	**<0.0001**	**71%**
	Control	-0.90 D (0.05)	-1.00 to -0.79	-	-		
Axial Length	Essilor® Stellest®	0.21 mm (0.02)	0.17 to 0.25	-0.24 (0.03)	-0.29 to -0.19	**<0.0001**	**53%**
	Control	0.45 mm (0.02)	0.42 to 0.49	-	-		

LS-Means: least-square means, ITT: Intent-to-Treat, SE: standard error, CI: confidence interval.

Age-based subgroup analysis showed treatment effectiveness across the three age subgroups (6-8 years old, 9-10 years old, and 11-12 years old), with 24-month SER reductions of 89%, 62%, and 72% respectively, representing mean differences of 1.08 D, 0.56 D, and 0.55 D. Similarly, both baseline myopia severity groups demonstrated a treatment effect, with lower myopia subjects (-0.75 to -2.50 D) experiencing a 71% reduction (0.56 D difference) and higher myopia subjects (-2.75 to -4.50 D) showing a 69% reduction (0.72 D difference) at 24 months. When analyzed by wearing time, both groups wearing less than 12 hours per day and those wearing 12 or more hours per day showed treatment effects of 75% and 69% respectively.

In the FIN-3101 study, safety information was collected when subjects were questioned by study investigators at each of the follow-up visits about possible symptoms, problems or complaints with the spectacles. **Table 4** provides details on the incidence of symptoms, problems, and complaints in the test and control subjects. The “Other symptoms” category in Table 4 includes symptoms such as itchy eyes, squinting, stinging sensations, very infrequent dizziness, rare shadows and afterimages when looking at bright light. None of these symptoms, problems, and complaints noted in Table 4 occurred at substantially higher rates in the test arm compared to the control arm.

Twenty-one ocular adverse events were reported in eleven subjects (nine in test group, twelve in control group). None of the events were classified as lens-related or significant by study investigators. The most common ocular adverse event reported was conjunctivitis (bacterial, allergic, or unknown). Best corrected visual acuity remained stable throughout the study, with no subjects in either group showing a worsening of two or more lines compared to baseline. These results are summarized in **Table 5.**

The test lens demonstrated acceptable safety and tolerability in the FIN-3101 study. Best corrected visual acuity remained stable throughout the study, with no subjects in either group showing a worsening of two or more lines compared to baseline.

Table 1: Summary of symptoms, problems and complaints - Participants dispensed study lenses.

	Test	Control
No. of Subjects	74	75
1. Symptoms		
i. Headache	2 (3%)	4 (5%)
ii. Halos	1 (1%)	2 (3%)
iii. Glare	0 (0%)	0 (0%)
iv. Blurred vision		
▪ Distance	5 (7%)	9 (12%)
▪ Near	2 (3%)	2 (3%)
▪ General	7 (9%)	6 (8%)
v. Double vision	1 (1%)	0 (0%)
vi. Other	3 (4%)	7 (9%)
2. Other		
i. Problems with frames	10 (14%)	10 (13%)
ii. Problems with lenses	4 (5%)	8 (11%)
iii. Other	0 (0%)	2 (3%)

Table 5: Best corrected distance visual acuity by visit and treatment (n(%))- Participants dispensed study lenses

	Baseline		6-Month		12-Month		18-Month		24-Month	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
No. of Eyes	148	150	148	140	146	138	140	130	138	132
>20/20	45 (30%)	60 (40%)	72 (49%)	66 (47%)	66 (45%)	54 (39%)	64 (46%)	63 (48%)	69 (50%)	65 (49%)
20/20	92 (62%)	81 (54%)	69 (47%)	65 (46%)	77 (53%)	74 (54%)	73 (52%)	62 (48%)	65 (47%)	65 (49%)
20/25	11 (7%)	9 (6%)	7 (5%)	9 (6%)	3 (2%)	9 (7%)	3 (2%)	5 (4%)	4 (3%)	2 (2%)
20/30	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<20/30	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

NOTE: Data in the FIN-3101 study was reported in logMAR. The following is the conversion from logMAR to Snellen reported in the table above:
<0.00 = >20/20
0.00 to 0.04 = 20/20 (20/20 – 20/21.9)
0.06 to 0.12 = 20/25 (20/23 – 20/26.4)
0.14 to 0.20 = 20/30 (20/27.6 – 20/31.7)
>0.20 = <20/30

FIN-3102 sub-study summary:

In the FIN-3102 sub-study to evaluate safety risks related to the design of the device, visual performance tests including, reading speed, contrast sensitivity, and effects of glare on visual acuity, were conducted on 88 of the 149 dispensed subjects from the FIN-3101 study. The visual performance tests used in this sub-study were not adequately validated to be used for the intended patient population (children aged 6 to 12 years). Thus, there is significant uncertainty in the interpretation of the results of these visual performance tests.

Rebound assessment:

Essilor provided an assessment showing a continuing cumulative treatment effect based on the 24-month clinical study results and also provided a summary of rebound literature available for their device. This information provided preliminary evidence that any potential rebound effect would likely not negate the observed treatment effect for their device but supported the need for a postmarket rebound study to confirm the information provided.

Pediatric Extrapolation:

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population. The device is indicated for pediatric patients 6-12 years old and those patients were enrolled in the clinical study (see Table 2).

POSTMARKET EVALUATION

A postmarket study will be conducted to evaluate whether there is a "rebound effect." The 12 month study will evaluate the change in axial length and spherical equivalent refractive error experienced by subjects after cessation of treatment with the Essilor® Stellest® spectacle lenses, as compared to a control group wearing single vision spectacle lenses. The study will also evaluate all observed ocular adverse events.

LABELING

The labeling is sufficient and satisfies the requirements of 21 CFR 801.109 for prescription devices.

There is a Healthcare Professional Fitting Guide as well as a Patient and Caregiver Guide. These two documents provide:

- a description of the device including the optical design elements and description of what lens tint(s) or coating(s) were used in clinical testing
- Description of how the device functions to slow the progression of myopia
- Recommended wearing schedule
- Spectacle fitting considerations

- A summary of the clinical study performed to support the device's safety and effectiveness in the intended use population, including a summary of the demographic and racial distribution of the study cohort.
- Warnings and precautions to ensure safe use of the device in the intended patient population.

The Patient and Caregiver Guide accompanies the device to be dispensed.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of prescription spectacle lenses to reduce the progression of myopia and the measures necessary to mitigate these risks.

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

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the prescription spectacle lenses to reduce the progression of myopia are 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.

BENEFIT-RISK DETERMINATION

The probable risks of the Essilor® Stellest® device are based on data collected in the FIN-3101 clinical study described above as well as risks generally associated with device based on the device characteristics and design. The risk of symptoms based on the reports obtained by open-ended questions in the clinical trial include visual halos and blurred vision.

The probable benefits of the device are also based on clinical effectiveness data collected in the clinical study as described above. The 2-year clinical study results show that the device significantly slows the progression of myopia in the test group as compared to the control group (-0.64 D SER and 0.24mm AL). The benefit of slowing myopia progression lies in its potential to prevent the sight threatening complications of myopia, particularly high myopia. The Essilor®

Stellest® spectacle lenses slow the progression of myopia as compared to a control group in the FIN-3101 study. This can help to mitigate risk factors for pathologic myopia: high refractive error and axial elongation.

Additional factors evaluated in determining probable risks and benefits for the Essilor® Stellest® spectacle lenses included consideration of the impact of the optical components of the Essilor® Stellest® lenses to interfere with reading, learning to read, and detection of obstacles in peripheral vision. Although there remains significant uncertainty regarding the risks associated with these vision-related activities, the overall benefit/risk associated with the use of the device was deemed acceptable based on available safety data, the effectiveness outcomes of the clinical trial, the preliminary assessment of a potential rebound effect, as well as the specific lens design, which included a 9mm clear central zone. A postmarket surveillance study was determined to be necessary to reduce the uncertainty regarding the potential for rebound following cessation of treatment with the Stellest® spectacle lenses.

The only currently FDA-approved intervention for reduction in myopia progression is a contact lens for daily wear which is approved for children aged 8 to 12 years. The Essilor® Stellest® lenses are indicated for children aged 6 to 12 years old. Thus, Essilor® Stellest® will meet an unmet need among children aged 6 to 7 years. In addition, the Essilor® Stellest® lenses are a lower risk device compared to contact lenses, since spectacle lenses do not carry the risk of eye infections such as microbial keratitis. This wider age range and lower risk provides probable benefits to young children at risk of myopia progression.

Patient Perspectives

A symptoms questionnaire was administered during the pivotal clinical trial. However, there was a lack of evidence to show that the questionnaire measured what it was intended in the trial. Therefore, the data were deemed uninterpretable and could not be used in the benefit-risk assessment.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> 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 the 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.

The probable benefits outweigh the probable risks for the Essilor® Stellest® spectacle lenses. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Essilor® Stellest® is granted and the device is classified as follows:

Product Code: QUR
Device Type: Prescription spectacle lenses to reduce the progression of myopia
Regulation Number: 21 CFR 886.5845
Class: II