September 29, 2022

NovaSight Ltd.
℅ Lee Kramm
President, Chief Strategist and Medical Officer
Regulatory Pathways Group, Inc.
340 S. Lemon Ave. #2471
Walnut, California 91789

Re: K221375
Trade/Device Name: CureSight-CS100
Regulation Number: 21 CFR 886.5500
Regulation Name: Digital Therapy Device For Amblyopia
Regulatory Class: Class II
Product Code: QQU
Dated: August 25, 2022
Received: August 29, 2022

Dear Lee Kramm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Elvin Ng
Assistant 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221375

Device Name
CureSight CS100 System

Indications for Use *(Describe)*
The CureSight™ system is indicated for improvement in visual acuity and stereo acuity in amblyopia patients, aged 4 - <9 years, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. CureSight™ is intended for both previously treated and untreated patients and is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the anaglyph glasses during CureSight™ treatment. CureSight™ is intended for prescription use only, in an at-home environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K221375

APPLICANT:	NovaSight Ltd. 1 Hayarden St. Airport City 7019801 Israel
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DATE SUMMARY PREPARED:	September 28, 2022
TRADE/MODEL NAME:	CureSight™-CS100 system
COMMON NAME:	Digital Therapy Device For Amblyopia
DEVICE CLASSIFICATION / CODE	886.5500, Class II QQU
PREDICATE DEVICE:	Luminopia One DEN210005 (October 20, 2021)

DEVICE DESCRIPTION

The CureSight™ system is an eye-tracking-based system aimed for improving visual acuity and stereo acuity under dichoptic conditions. The technology is based on real-time eye tracking and separation of the visual stimuli presented on a monitor into two separate digital channels, one for each eye. Using this dichoptic method, any streamed video content can be tailored individually per eye and then presented simultaneously to each eye.

During the treatment, dichoptic anaglyph (red-blue) glasses that are part of the CureSight system are to be worn over the habitual spectacle correction.

The CureSight™ system comprises the following components/modules:

- CureSight-CS100 device (console and anaglyph glasses)
- CureSight Web-App/Portal

CureSight™ system is aimed for improving visual acuity and stereo acuity under dichoptic conditions, using digital content in pediatric patients (age 4 to <9 years) suffering from amblyopia, under a supervision of eye care provider.

In accordance with the intended use of this device, the CureSight™ system treatment sessions include 90 minutes per day, 5 days a week for 16 weeks, with an overall cumulative time of approximately 120 hours. During treatment, patients wear anaglyph glasses which are included as part of the CureSight™-CS100 device. The user interacts with the system through the user interface, by manually selecting digital content, such as movies, using the device media touchscreen interface.

Streaming video information is altered by the software algorithm and is simultaneously presented in different colors (anaglyph conversion) on the video display for both the non-amblyopic eye and amblyopic eye. The video information is separated through the use of anaglyph glasses worn by the patient to produce a dichoptic presentation.

The eye tracker dynamically tracks the gaze position of each eye and provides real-time measurement of ocular gaze parameters. The gaze position in combination with the physical position of the patient's eyes in space are used as input for the image processing as part of the treatment.

A real-time software algorithm dynamically blurs the central image area of a streaming video display for the non-amblyopic eye of a patient, thereby forcing the patient's visual system to use the information from the central vision area of the amblyopic eye. Size and intensity of the blur depends upon the degree visual acuity of both eyes.

INDICATIONS FOR USE

The CureSight™ system is indicated for improvement in visual acuity and stereo acuity in amblyopia patients, aged 4-<9 years, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. CureSight™ is intended for both previously treated and untreated patients and is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the anaglyph glasses during CureSight™ treatment. CureSight™ is intended for prescription use only, in an at-home environment.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The CureSight™-CS100 system described in this 510(k) premarket notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed Class II predicate device, the Luminopia One. Table 1 provides a technological comparison of the CureSight™-CS100 system compared to the predicate device (DEN210005). Both devices are intended to improve visual acuity of patients with amblyopia.

Both the CureSight™-CS100 system and the predicate devices provide video-based treatment. While the CureSight™-CS100 system includes hardware for the presentation of dichoptic information, the Luminopia One is software as a medical device (SaMD) that relies on 3rd party hardware to achieve the same functionality. The display technology employed by both devices represents the same ocular safety profile for illumination sources.

The CureSight™-CS100 system hardware components have been verified and validated through performance evaluation as well as Human Factors testing to ensure that no new issues of safety and effectiveness are raised by the CureSight™-CS100 system.

TABLE 1
TECHNOLOGICAL COMPARISON OF THE CURESIGHT-CS100 TO THE PREDICATE DEVICE

Characteristic	CureSight (CS100) Proposed Device	Luminopia One DEN210005 Predicate Device	Comparison
Regulation/Product Code	886.5500; QQU, Digital Therapy Device for Amblyopia	886.5500; QQU, Digital Therapy Device for Amblyopia	Same
Intended use	To improve visual acuity of patients with amblyopia	To improve visual acuity of patients with amblyopia	Same
Target Population	Pediatric patients aged 4 to < 9 years	Pediatric patients aged 4 to 7 years	Similar
Indications for use	The CureSight™ system is indicated for improvement in visual acuity and stereo acuity in amblyopia patients, aged 4-<9 years, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. CureSight™ is intended for both previously treated and untreated patients and is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the anaglyph glasses during CureSight™ treatment. CureSight™ is intended for prescription use only, in an at-home environment.	Luminopia One is indicated for improvement in visual acuity in amblyopia patients, aged 4 to 7, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. Luminopia One is intended for both previously treated and untreated patients; however, patients with more than 12 months of prior treatment (other than refractive correction) have not been studied. Luminopia One is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the HMD during Luminopia One therapy. Luminopia One is intended for prescription use only, in an at-home environment.	Similar
Anatomical Sites	Eyes; binocular	Eyes; binocular	Same
Use Environment	Prescription - Home use (patient); Remote monitoring by Eyecare Professional	Prescription - Home use (patient); Remote monitoring by Eyecare Professional	Same
Characteristics			
Therapy Type	Digital therapy device for amblyopia	Digital therapy device for amblyopia	Same
Fundamental Technology	The device digitally modifies images or videos such that they are perceived differentially by the amblyopic eye and the non-amblyopic (fellow eye).	The device digitally modifies images or videos such that they are perceived differentially by the amblyopic eye and the non-amblyopic (fellow eye).	Similar

Characteristic	CureSight (CS100) Proposed Device	Luminopia One DEN210005 Predicate Device	Comparison
	Video display device/console contains visual information for each eye using different colors (anaglyph conversion). Eye tracking is used to alter the video stream to dynamically adjust the video image for the gaze position for each eye. Separation of the visual information is achieved by anaglyph glasses resulting in a dichoptic presentation, with the non-amblyopic eye image blurred. Software treatment algorithms and the digital therapy device hardware. The visual information presented to one eye is complementary to that for the other eye to encourage binocular fusion.	Head mounted display (3rd party HMD unit) contains visual information for each eye in separate video channels to a produce a dichoptic presentation, with the non-amblyopic eye image of reduced contrast The visual information presented to one eye is complementary to that for the other eye to encourage binocular fusion.	
Hardware platform	• Video console with integrated eye tracker • Anaglyph glasses	• 3rd party head mounted display • 3rd party Android mobile device	Different
Software platform	• CureSight-CS100 software • CureSight Web Portal	• Luminopia One software • Luminopia One Web Portal	Similar
Video display relay method	Separation of the visual information is achieved by anaglyph glasses and real time color conversion resulting in a dichoptic presentation.	Physically separate displays for amblyopic and non-amblyopic (fellow) eyes	Different
Treatment Plan **Prescription or OTC**	Rx Only	Rx Only	Same
Treatment duration/ frequency	1.5 hour/day; 5 days per week	1 hour/day; 6 days per week	Similar
Eyecare Provider Involvement	Online portal to monitor both treatment completion progress and compliance (recommended time)	Online portal to monitor both treatment completion progress and compliance (recommended time)	Same

PERFORMANCE DATA

Bench Testing

The non-clinical bench testing performed on the CureSight™-CS100 system consisted of design verification and functional product testing, packaging, transportation, electrical safety, EMC, software validation and Human Factors/Usability Engineering according to the following list of applicable standards:

- EN 60601-1:2005/A1:2012+A2:2020
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014; EN 60601-1-2:2015
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2020
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Usability
- AAMI/ANSI HE75:2009/(R) 2013
  Human Factors Engineering – Design of Medical Devices
- IEC 62366-1:2020
  Medical devices – Part 1: Application of usability engineering to medical devices.

The device was evaluated to verify the design outputs met the original design input requirements and intended use. Results of the non-clinical bench testing demonstrate that the CureSight™-CS100 system meets the defined specifications and functional requirements that are well defined and sufficient to establish equivalence to the predicate device.

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "Moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury or delay of treatment to the patient through incorrect or delayed information or through the action of a care provider.

Clinical Performance Evaluation

A pivotal study was performed to compare the binocular treatment with the CureSight™-CS100 system to traditional treatment. This study was a prospective, multicenter, randomized, evaluator-masked, controlled non-inferiority pivotal trial designed to assess the safety and effectiveness of the CureSight™, eye-tracking-based treatment under binocular conditions versus the standard of care, occlusive patching. Participants were aged 4-9 years with unilateral amblyopia associated with anisometropia, mild strabismus, or both. A total of 103 subjects were enrolled across six sites - 51 subjects were randomized to the study arm (CureSight binocular treatment) and 52 subjects were randomized to the control arm (patching of non-amblyopic eye).
Study subjects were required to have VA measured in each eye without cycloplegia in current spectacle correction (if applicable) within 7 days prior to randomization using the Lea symbol per ATS VA protocol for children < 7 years and the E-ETDRS VA protocol for children ≥ 7 years on a study-approved device displaying single surrounded optotypes, as follows:

a. Visual acuity in the amblyopic eye 20/32 to 20/100 inclusive
b. Best-corrected dominant-eye VA meeting the following criteria:
    - If age 4, 20/40 or better by Lea symbol per ATS
    - If age 5 and older, 20/32 or better by ATS-HOTV using LEA symbols for age <7 and Lea numbers for > 7 years
c. Interocular difference ≥ 2 logMAR lines (Lea symbol per ATS)

Participants assigned to the binocular treatment group were prescribed the CureSight treatment to watch for 90 minutes per day, five days per week for 16 weeks. Participants assigned to control group were prescribed to wear an adhesive patch over the dominant eye for 2 hours per day, seven days per week for 16 weeks.

All participants were asked to wear their habitual optical correction regularly during the entire study period. Participants in the treatment group were instructed to always wear optical correction glasses under the anaglyph red-blue glasses.

The primary effectiveness endpoint for this study was:

Change (improvement) from baseline in Distance VA of the amblyopic eye (AEDVA) to week 16 in both study groups. The improvement is calculated as the difference between the baseline AEDVA and the AEDVA at each visit. Success Criterion: If the improvement in amblyopic eye distance VA (AEDVA) of the Binocular treatment (CureSight) group from baseline to 16 weeks is not inferior to that of the amblyopic eye of the control (patching) group within a margin of -0.10 logMAR, then the primary effectiveness endpoint will have been successfully met.

The secondary effectiveness endpoints for this study were:

- Change from baseline in stereo acuity score (Randot preschool test) score to week 16 as measured in arcseconds in the treatment group.
- Change from baseline in binocular distance VA to week 16 as measured in LogMAR in the treatment group.
- Change from baseline in binocular distance VA to week 16 as measured in LogMAR compared between the treatment and control groups.

- Change from baseline in stereo acuity (Randot preschool test) score to week 16 as measured in arcseconds compared between the treatment and control groups.

Safety outcomes consisted of:

- Incidence of Adverse Events
  - The frequency, severity, and causality of adverse events (AEs), related and un-related to binocular treatment and occurring during the study in the treatment and control groups.
- Distance VA of the Fellow Eye
  - Change from baseline in Distance VA of the fellow eye (FEDVA) to week 16 in both study groups.
  - The proportion of subjects with loss of 0.2 or more logMAR lines (10 or more letters) of FEDVA from baseline to the 16-week exam in the treatment and control groups.
- Ocular Alignment
  - The proportion of subjects with development of new strabismus (no heterotropia at baseline and the presence of near and/or distance heterotropia at 16 weeks) or an increase from baseline ≥10Δ in a pre-existing strabismus at 16 weeks in the two arms.
- Diplopia (ATS Diplopia Questionnaire)
  - The proportion of subjects with each level of diplopia in both study arms.
- Adverse Symptoms and Events using a 5-item symptom survey regarding the presence of various ocular symptoms in both study arms.

The subjects enrolled in the study were between 4 and < 9 years of age. The mean age was 6.6 (SD 1.3) years in the CureSight arm and 6.9 (1.4) years in the patching arm; the percentage of female subjects was 45% in the CureSight arm and 56% in the patching arm.

Nearly all of the subjects in the CureSight arm (98%) and all of the subjects in the patching arm (100%) were listed as Caucasian, however both study arms included children who had at least one parent whose place of origin was Middle East or Africa. In the CureSight group, the other 2% of subjects were listed as Pacific Islander.

The primary and secondary endpoints results are reported based on the modified intent-to-treat (mITT) analysis, which established the study's statistical conclusions. At 16 weeks, amblyopic eye distance visual acuity (AEDVA) improved by 2.63 lines (95% CI [2.24, 3.03] lines, N=50) in the study treatment group and 2.29 lines (95% CI [1.93, 2.66] lines, N=50) in the control group. The difference between groups at week 16 was 0.34 line (90% CI [-0.08, 0.76] line); the lower bound of the 90% CI is greater than the pre-specified non-inferiority margin, -1 line (-0.1 LogMAR); therefore, the null hypothesis is rejected, CureSight is found non-inferior to Patching, and the study is deemed successful.

TABLE 2 AMBLYOPIC EYE DVA[1] – MODIFIED INTENT-TO-TREAT (MITT) POPULATION				**Results**
	Treatment Group N=50	**Control Group N=50**	**Difference in Change in BCVA[2] (90% CI)**	**Decision**
Improvement from Baseline at 16 Weeks (lines)[3]	**2.81 ± 1.32 (43) 2.6 (0, 6.0) 2.63 [2.24, 3.03]**	**2.34 ± 1.36 (49) 2.2 (0, 6.0) 2.29 [1.93, 2.66]**	**0.34 (-0.08, 0.76)**	**Reject H_0 Establish Non-inferiority**
Change from Baseline at 16 Weeks (logMAR)	0.28 ± 0.13 (43) 0.26 (0, 0.60) 0.26 [0.22, 0.30]	0.23 ± 0.14 (49) 0.22 (0, 0.60) 0.23 [0.19, 0.27]		
Baseline (logMAR)	0.37 ± 0.15 (50) 0.37 (0.14, 0.70)	0.37 ± 0.14 (50) 0.39 (0.16, 0.70)		
16 Weeks (logMAR)	0.08 ± 0.13 (43) 0.08 (-0.20, 0.50)	0.13 ± 0.14 (49) 0.10 (-0.20, 0.44)		

[1] Based on mITT data of all participants who retrospectively met study criteria. Data presented as mean ± standard deviation (N) median (min, max). Change from baseline also includes Least-Squares means (model adjusted means); LSmean [95% CI]. For LSmeans, imputation for missing data is addressed in the statistical model (repeated measures analysis of covariance).

[2] Difference between groups (treatment - control) and 90% confidence interval are based on the LSmean difference between the treatment groups derived from the visit by treatment group interaction term from the repeated measures ANCOVA model. Positive difference between groups represents larger improvement in the treatment group.

[3] Original visual acuity measurements captured using logMAR. A 1-line improvement from baseline corresponds to a change of 0.10 logMAR.

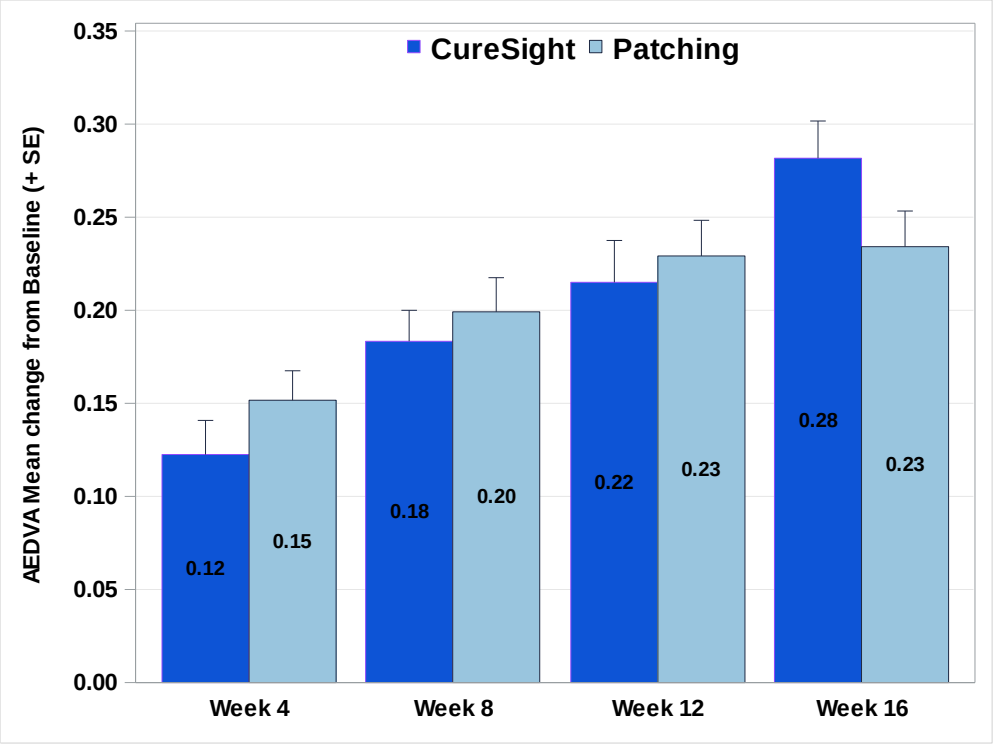

FIGURE 1 AEDVA MEAN CHANGE FROM BASELINE AT EACH VISIT (IN LOGMAR) – MITT SET

Note: Error bars refer to standard error. Week 4: N=45 (CS), N=46 (P); Week 8: N=44 (CS), N=47 (P); Week 12: N=44 (CS), N=46 (P); Week 16: N=43 (CS), N=49 (P), where CS refers to CureSight group and P refers to Patching group.

TABLE 3 IMPROVEMENT IN AMBLYOPIC EYE VA ≥ 2 LINES[1] – MITT POPULATION

	Treatment Group N=50	Control Group N=50
Improvement ≥ 2 lines from Baseline to 4 weeks	20.0% (9/45)	39.1% (18/46)
Improvement ≥ 2 lines from Baseline to 8 weeks	36.4% (16/44)	51.1% (24/47
Improvement ≥ 2 lines from Baseline to 12 weeks	47.7% (21/44)	63.0% (29/46)
Improvement ≥ 2 lines from Baseline to 16 weeks	79.1% (34/43)	61.2% (30/49)

[1]Based on participants with available data at each visit. Data presented as: % (n/N)

TABLE 4 DISTRIBUTION OF LINE CHANGE IN DVA OF AMBLYOPIC EYE BY VISIT[1] – MITT POPULATION

	4 Weeks		8 Weeks		12 Weeks		16 Weeks	
Number of Lines Change (follow-up - baseline)[2]	**CS**	**Control**	**CS**	**Control**	**CS**	**Control**	**CS**	**Control**
≥6-line improvement	0.0% (0/45)	0.0% (0/46)	0.0% (0/44)	0.0% (0/47)	2.27% (1/44)	0.0% (0/46)	2.33% (1/43)	2.04% (1/49)
5-<6 lines improvement	0.0% (0/45)	0.0% (0/46)	0.0% (0/44)	2.13% (1/47)	2.27% (1/44)	4.35% (2/46)	4.65% (2/43)	4.08% (2/49)
4-<5 lines improvement	2.22% (1/45)	2.17% (1/46)	6.82% (3/44)	8.51% (4/47)	4.55% (2/44)	13.04% (6/46)	13.95% (6/43)	10.20% (5/49)
3-<4 lines improvement	6.67% (3/45)	13.04% (6/46)	9.09% (4/44)	14.89% (7/47)	25.0% (11/44)	10.87% (5/46)	27.91% (12/43)	18.37% (9/49)
2-<3 lines improvement	11.11% (5/45)	23.91% (11/46)	20.45% (9/44)	25.53% (12/47)	13.64% (6/44)	34.78% (16/46)	30.23% (13/43)	26.53% (13/49)
1-<2 lines improvement	33.33% (15/45)	32.61% (15/46)	38.64% (17/44)	31.91% (15/47)	13.64% (15/44)	34.78% (10/46)	9.30% (4/43)	24.49% (12/49)
Less than1-line improvement	28.89% (13/45)	13.04% (6/46)	20.45% (9/44)	12.77% (6/47)	11.36% (5/44)	8.70% (4/46)	9.30% (4/43)	6.12% (3/49)
No change	11.11% (5/45)	10.87% (5/46)	4.55% (2/44)	2.13% (1/47	4.55% (2/44)	4.35% (2/46)	2.33% (1/43)	8.16% (4/49)
Up to 1-line decrease	4.44% (2/45)	4.35% (2/46)	0.0% (0/44)	0.0% (0/47)	0.0% (0/44)	2.17% (1/46)	0.0% (0/43)	0.0% (0/49)
>1-2 lines decrease	0.0% (0/45)	0.0% (0/46)	0.0% (0/44)	0.0% (0/47)	2.27% (1/44)	0.0% (0/46)	0.0% (0/43)	0.0% (0/49)
> 2 lines decrease	2.22% (1/45)	0.0% (0/46)	0.0% (0/44)	2.13% (1/47)	0.0% (0/44)	0.0% (0/46)	0.0% (0/43)	0.0% (0/49)

[1] Based on participants with available data at each visit. Categorical variables presented as n/N (%) where N is the number of participants with available data.

[2] Original visual acuity measurements captured using logMAR. A 1-line improvement from baseline corresponds to a change of 0.10 logMAR.

At week 16, the median change from baseline in stereo acuity (Randot preschool test) demonstrated a significant improvement by 0.40 log arcseconds in the study treatment group (Range: -0.65 to 1.77, P<0.0001, N=43). Mean binocular distance visual acuity significantly improved from baseline to week 16 by 1.29 lines (95% CI [1.01, 1.58] lines, P<0.0001, N=43) in the study treatment group. The improvement from baseline to week 16 in Randot stereo acuity and binocular DVA was not significantly different between CureSight and patching groups.

TABLE 5 STEREO ACUITY (RANDOT)[1] – MODIFIED INTENT-TO-TREAT (MITT) POPULATION				
	Treatment Group N=50	**P-value[2]**	**Control Group N=50**	**Between-groups P-value**
Improvement from Baseline at 16 weeks (log arcseconds)	**0.40 (-0.65, 1.77) N=43**	**<.0001**	**0.40 (-0.60, 1.95) N=48**	**0.76**
Baseline (log arcseconds)	2.00 (1.60, 3.55) N=49		2.30 (1.60, 3.55) N=49	
16 Weeks (log arcseconds)	1.78 (1.60, 3.55) N=43		2.00 (1.60, 3.55) N=49	

[1] Based on mITT data of all participants with data available at baseline and each visit. Data presented as median (min, max) N. Stereo acuity measured with Randot preschool test.

[2] P-value based on one-sample Wilcoxon test for change from baseline in the treatment group and two-sample Wilcoxon test for between-groups comparison

TABLE 6 BINOCULAR DVA[1] – MODIFIED INTENT-TO-TREAT (MITT) POPULATION				
	Treatment Group N=50	**P-value[2]**	**Control Group N=50**	**Between-groups P-value**
Improvement from Baseline at 16 weeks (lines)	**1.29 ± 0.92 [1.01, 1.58] N=43**	**<.0001**	**0.88 ± 1.16 [0.55, 1.21] N=49**	**0.0653**
Change from Baseline at 16 weeks (logMAR)	0.13 ± 0.09 [0.10, 0.16] N=43		0.09 ± 0.12 [0.06, 0.12] N=49	
Baseline (logMAR)	0.08 ± 0.12 N=50		0.05 ± 0.11 N=50	
16 Weeks (logMAR)	-0.06 ± 0.10 N=43		-0.04 ± 0.09 N=49	

[1] Based on mITT data of all participants with data available at baseline and each visit. Data presented as mean ± SD [95% CI] N

[2] P-value based on one-sample t-test for change from baseline and two-sample t-test for between-groups comparison.

Median adherence (i.e., compliance with treatment regimen as prescribed) with the CureSight device over 16 weeks was 91% (N=43). Median adherence with patching in the control group over 16 weeks was 83% (N=49). Primary outcome data was missing for 11 / 103 participants at week 16.

Adverse Events

The adverse events observed in the study are reported based on all enrolled participants (ITT population). There were no serious AEs in the study. The overall incidence of non-serious adverse events was 27.4% (14/51) in the treatment group and 26.9% (14/52) in the control group. Two of 51 subjects (3.9%) in the CureSight arm and 5 of 52 subjects (9.6%) in the patching arm had AEs that were possibly related to treatment. The large majority of AEs were mild. AEs were reported as moderate in severity in 2.0% of the subjects in each group.

The most commonly reported AEs in the CureSight study were related to pathogens and allergy in 17.7% (9/51) subjects in CureSight group and 11.5% (6/52) subjects in patching group, including those related to COVID-19. The next most common AEs in the CureSight group were headache and worsening VA in the amblyopic eye. Headache was reported by 3.9% (2/51) subjects in the CureSight group compared to 7.7% (4/52) in the patching group. Worsening VA in the amblyopic eye was reported in 3.9% (2/51) subjects in the CureSight group, and in no subjects in the patching group. Worsening of baseline heterotropia (≥ 10 PD) was reported in 2.0% (1/51) subjects in the CureSight group and no cases reported in the patching group. On the other hand, new heterotropia (not present at baseline) was not reported in the CureSight group, and was reported in 3.9% (2/52) subjects in the patching group. Other notable risks that were not observed as Adverse Events in CureSight or patching group were diplopia, eye strain, skin irritation and seizures. No subject in the CureSight group had 2-line or greater loss in fellow eye DVA at week 16. Mean DVA change in the fellow eye, from baseline to week 16, was 0.08 logMAR (SD 0.10) in the CureSight group and 0.06 logMAR (SD 0.13) in the patching group.

TABLE 7 NON-SERIOUS ADVERSE EVENTS[1] (UNRELATED AND RELATED TO TREATMENT) – ITT POPULATION

	Treatment Group (N=51)	**Control (Patching) Group (N=52)**
Diplopia	0 (0.0%) [0]	0 (0.0%) [0]
New heterotropia[2]	0 (0.0%) [0]	2 (3.9%) [2]
Worsening heterotropia[3]	1 (2.0%) [1]	0 (0.0%) [0]
Worsening VA[4] (amblyopic eye)	2 (3.9%) [2]	0 (0.0%) [0]
Worsening VA[4] (fellow eye)	0 (0.0%) [0]	1 (1.9%) [1]
Headache	2 (3.9%) [2]	4 (7.7%) [5]
Eye strain	0 (0.0%) [0]	0 (0.0%) [0]
Skin Irritation	0 (0.0%) [0]	0 (0.0%) [0]
Seizures	0 (0.0%) [0]	0 (0.0%) [0]
Pathogens and Allergy[5]	9 (17.7%) [12]	6 (11.5%) [6]
Other[6]	0 (0.0%) [0]	2 (3.9%) [2]
Overall	14 (27.4%) [17]	14 (26.9%) [16]

TABLE 7 NON-SERIOUS ADVERSE EVENTS[1] (UNRELATED AND RELATED TO TREATMENT) – ITT POPULATION		
	Treatment Group (N=51)	**Control (Patching) Group (N=52)**

[1] Includes all adverse events in all enrolled subjects (ITT population), even if classified as Not Related to study treatment. Data presented as: n (%) [m], where n is number of participants with event and m is the number of events. Participants may experience more than one AE.
[2] New ocular deviation in a participant without a tropia at baseline
[3] Increase in ocular deviation ≥ 10Δ in a participant with a tropia at baseline
[4] Decrease ≥ 2 logMAR lines from baseline
[5] Includes seasonal allergies and viral infections, including COVID-19
[6] Other AEs in control group include rage attack and syncope

CONCLUSION

As described in this 510(k) Summary, the subject and predicate devices have the same intended use and similar indications for use. The minor differences in technological characteristics between the subject and predicate devices raise no new issues of safety or effectiveness. Performance testing and results from the clinical study further establish the safety and effectiveness of the subject device when used in accordance with its labeling. Therefore, the CureSight-CS100 System is substantially equivalent to the predicate Luminopia One device cleared under DEN210005.