April 9, 2025

Luminopia, Inc.
Scott Xiao
CEO
955 Massachusetts Ave #335
Cambridge, Massachusetts 02139

Re: K243819
Trade/Device Name: Luminopia
Regulation Number: 21 CFR 886.5500
Regulation Name: Digital Therapy Device For Amblyopia
Regulatory Class: Class II
Product Code: QQU
Dated: December 9, 2024
Received: December 12, 2024

Dear Scott Xiao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Y. Ng -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243819

Device Name

Luminopia

Indications for Use *(Describe)*

Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. Luminopia is indicated for improvement in visual acuity in amblyopia patients, aged 4 to <13, 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. Luminopia 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 therapy. Luminopia 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

510(k) Owner: Luminopia, Inc.
Address: 955 Massachusetts Ave #335, Cambridge, MA 02139
Phone: 857-365-6636
Fax: 857-336-6605
Contact Person: Scott Xiao
Date: Dec 9, 2024

Trade Name: "Luminopia One" and "Luminopia"
Common Name: N/A
Classification Name: Digital Therapy Device for Amblyopia (21 CFR 886.5500, Product Code: QQU)

Predicate Device: Luminopia (Submission Number: K233720)

Indications for Use: Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. Luminopia is indicated for improvement in visual acuity in amblyopia patients, aged 4 to <13, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. Luminopia is intended for both previously treated and untreated patients. Luminopia 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 therapy. Luminopia is intended for prescription use only, in an at-home environment.

Device Description:
Luminopia is Software as a Medical Device (SaMD) Mobile Application that is intended to improve vision in pediatric patients with amblyopia. The Mobile Application ("Mobile App") consists of two software units: the Video Content Platform and the Therapeutic Algorithms. The Video Content Platform allows the Patient to browse from a library of popular TV shows and movies and select videos to watch. The Video Content Platform, without the Therapeutic Algorithms, is analogous to consumer video applications (e.g., YouTube, Netflix). The Therapeutic Algorithms provide the actual treatment, by applying modifications to the videos shown by the Video Content Platform.

It is hypothesized that the Therapeutic Algorithms improve vision by breaking interocular suppression and encouraging amblyopic eye usage. The Therapeutic Algorithms are applied to patient-selected video content in the same manner for every video. The algorithms reduce contrast to the stronger eye's input to break interocular suppression and encourage amblyopic eye usage. Additionally, parts of each eye's input are occluded by dichoptic masks superimposed over the video content to promote binocular combination. The masks rotate through predefined pairs over the course of treatment.

The Mobile App is designed to be used with commercially available, off-the-shelf head-mounted displays ("HMDs") and does not require any hardware modifications or customization. These HMDs can either consist of a headset combined with a display unit or consist of an all-in-one unit. The HMD serves two functions. Firstly, the HMD serves as the computing platform for the Mobile App, analogous to a smartphone for a mobile medical application. The HMD requires a Wi-Fi connection to run the Mobile App. Secondly, the HMD serves as a viewing device for dichoptic presentation of the content in the app, similar to a stereoscope device (FDA Product Code: HJR). During usage, the Mobile App displays a separate image to each of the Patient's eyes within the HMD, and the images appear as one when viewed together.

All compatible HMDs meet the following set of minimum requirements:

Parameter	**HMD**
Luminance and luminance uniformity	≥ 48 cd/m^2
Michelson contrast (low spatial frequency)	≥ 90% across field of view
Michelson contrast (high spatial frequency grille pattern)	Baseline requirement
Resolution	≥ 14.0 pixels/degree (vertical) ≥ 14.4 pixels/degree (horizontal)
IPD range support	Meets requirements ≥ 52mm IPD
Internet capability	Yes
Battery capacity	> 90 min
Weight	< 500 g (± 5%)
RF compliance	Yes
Audio support	Yes
Power button	Yes
Eye glasses compatibility	Yes
Processing capacity	> Snapdragon 821
Refresh rate	≥ 60 Hz
Field of view	≥ 51.9 degrees (horizontal) ≥ 30.6 degrees (vertical)

Substantial Equivalence:

Feature	**Subject Device**	**Cleared Device**	**Impact**

		(K233720)	
Class	II	II	No change
Classification	886.5500	886.5500	No change
Product code	QQU	QQU	No change
Labeling			
Indications for Use	Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. Luminopia is indicated for improvement in visual acuity in amblyopia patients, aged 4 to <13, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. Luminopia is intended for both previously treated and untreated patients. Luminopia 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 therapy. Luminopia is intended for prescription use only, in an at-home environment.	Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. Luminopia is indicated for improvement in visual acuity in amblyopia patients, aged 4-7, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional. Luminopia 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 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 therapy. Luminopia is intended for prescription use only, in an at-home environment.	Similar
Prescription/ over-the-counter use	Prescription-use only	Prescription-use only	No change
Use environment	Home use	Home use	No change

Compatible HMDs listed in labeling	- DPVR P1 Pro 4K - Pico G2 4K	- DPVR P1 Pro 4K - Pico G2 4K	No change
Technological Characteristics			
Device type	Software as a Medical Device (SaMD)	Software as a Medical Device (SaMD)	No change
Device design	2 software-only components: - Mobile Application - Backend Service Layer	2 software-only components: - Mobile Application - Backend Service Layer	No change
Device materials	N/A (device is SaMD)	N/A (device is SaMD)	No change
Energy source	N/A (device is SaMD)	N/A (device is SaMD)	No change
Device feature: Therapeutic mechanism	Modification of visual stimuli using: contrast reduction + dichoptic masks	Modification of visual stimuli using: contrast reduction + dichoptic masks	No change
Device feature: Visual stimuli	Video content	Video content	No change
Hardware platform	Off-the-shelf Head-Mounted Display (HMD)	Off-the-shelf Head-Mounted Display (HMD)	No change

There were no changes to the Luminopia device in this submission from the predicate device, and therefore, there are no changes to the technological characteristics.

The change in the Indications for Use represent a label expansion for older children and is supported by clinical performance data.

Performance Data:

Clinical Performance Evaluation

The safety and efficacy of Luminopia for 4 to <8-year-old patients with amblyopia was established in DEN210005. This Clinical Performance Evaluation describes effectiveness of Luminopia in improving vision in children aged 4 to <13 in a real-world study in accordance with FDA Guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.

Luminopia was evaluated in a Real-World Registry study, designed prospectively, which collected retrospective data from medical health records of patients treated with Luminopia under usual care. The registry employed an all-comers design and included any patient with an

amblyopia diagnosis and Luminopia use of at least 12 weeks, and only excluded patients who had taken part in past Luminopia clinical trials. Visual Acuity change from the time of Luminopia prescription to the last visit in the registry study was reported. The registry included 334 patients, of whom 290 were aged 4 to <13 with a diagnosis of amblyopia associated with anisometropia and/or strabismus.

The registry study patients had an average of 2.8 years in refractive correction and 1.8 years using patching and/or atropine before starting Luminopia. Patients used Luminopia treatment for an average of approximately 8.2 months. Across all patients aged 4 to <13 with a diagnosis of amblyopia associated with anisometropia and/or strabismus, the mean amblyopic eye best-corrected visual acuity (BCVA) improved 1.1 lines (95% CI: 0.92-1.3 lines, N=290). For the subgroup of patients aged 4-7, the mean amblyopic eye best-corrected visual acuity (BCVA) improved 1.2 lines (95% CI: 1.0-1.4 lines, N=186). For the subgroup of patients aged 8-12, the mean amblyopic eye best-corrected visual acuity (BCVA) improved 0.95 lines (95% CI: 0.66-1.3 lines, N=104).

The Adverse Event risk profile of Luminopia has been established through DEN210005. The risks of Luminopia reported through real-world data is lower than the risk reported within the RCT, with only 9 (3%, N=290) non-serious adverse events reported, although this is likely due to underreporting in the real-world environment. The risk of Luminopia in 4-12-year-olds is expected to be similar to the risk for 4-7-year-olds, as established in DEN210005.

Amblyopic Eye Change in BCVA[1]			
	Baseline	**Last Visit**	**Improvement in BCVA (Lines)[2]**
Age 4-7	0.397 ± 0.211 (186) 0.4 (0.1, 1.18) [0.367, 0.428]	0.282 ± 0.219 (186) 0.18 (-0.12, 1.1) [0.250, 0.313]	**1.16 ± 1.4 (186)** **1.0 (-2.2, 5.2)** **[0.96, 1.36]**
Age 8-12	0.432 ± 0.231 (104) 0.4 (0.1, 1.3) [0.387, 0.477]	0.337 ± 0.216 (104) 0.3 (0.0, 1.0) [0.285, 0.379]	**0.95 ± 1.5 (104)** **0.9 (-2.0, 7.0)** **[0.66, 1.25]**
Age 4-12	0.410 ± 0.218 (290) 0.4 (0.1, 1.3) [0.384, 0.435]	0.301 ± 0.219 (290) 0.3 (-0.12, 1.1) [0.276, 0.327]	**1.08 ± 1.4 (290)** **1.0 (-2.2, 7.0)** **[0.92, 1.25]**

1. Based on participants with available data at baseline and one follow-up visit. Data presented as mean ± standard deviation (N) median (min, max). Change from baseline also includes [95% CI].
2. Original visual acuity measurements captured using logMAR. Change presented in Lines of Visual Acuity. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.

Amblyopic Eye Change in BCVA Over Time[1]						
	Time-point	**N**	**Mean[2]**	**Std Dev**	**Lower 95% CI**	**Upper 95% CI**
4 to 7	12 week - Baseline	135	1	1.19	0.79	1.2
	24 week - Baseline	91	1.12	1.3	0.85	1.39
	36 week - Baseline	68	1.22	1.41	0.88	1.57
	48 week - Baseline	44	1.28	1.47	0.84	1.73
	60 week - Baseline	10	0.92	1.84	-0.4	2.24
	72 week - Baseline	5	0.6	1.85	-1.7	2.9
8 to 12	12 week - Baseline	61	0.94	1.44	0.57	1.31
	24 week - Baseline	58	0.74	1.36	0.39	1.1
	36 week - Baseline	39	1.47	1.41	1.01	1.93
	48 week - Baseline	19	0.68	1.76	-0.16	1.53
	60 week - Baseline	7	2.26	2.44	0.01	4.51
	72 week - Baseline	1	0		0	0
4 to 12	12 week - Baseline	196	0.98	1.27	0.8	1.16
	24 week - Baseline	149	0.97	1.33	0.76	1.19
	36 week - Baseline	107	1.31	1.41	1.04	1.58
	48 week - Baseline	63	1.1	1.57	0.71	1.5
	60 week - Baseline	17	1.47	2.14	0.37	2.57
	72 week - Baseline	6	0.5	1.67	-1.25	2.25

1. Based on participants with available data at baseline and at the timepoint with +/- 6 week window.
2. Original visual acuity measurements captured using logMAR. Mean change presented in Lines of Visual Acuity. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.

Amblyopic Eye Change in BCVA[1]			
Number of Lines Change[2] (follow-up – baseline)	**Age 4-7**	**Age 8-12**	**Age 4-12**
6> to ≤7 line improvement	0.0% (0/186)	1.0% (1/104)	0.3% (1/290)
5> to ≤6 line improvement	0.5% (1/186)	1.0% (1/104)	0.7% (2/290)
4> to ≤5 line improvement	3.2% (6/186)	0.0% (0/104)	2.1% (6/290)
3> to ≤4 line improvement	3.8% (7/186)	5.8% (6/104)	4.5% (13/290)
2> to ≤3 line improvement	13.4% (25/186)	11.5% (12/104)	12.8% (37/290)
1> to ≤2 line improvement	31.7% (59/186)	25.0% (26/104)	29.3% (85/290)
0> to ≤1 line improvement	15.6% (29/186)	17.3% (18/104)	16.3% (47/290)
No change	22.6% (42/186)	26.0% (27/104)	23.8% (69/290)
0> to ≤1 line decrease	4.3% (8/186)	3.8% (4/104)	4.1% (12/290)
1> to ≤2 line decrease	4.3% (8/186)	8.7% (9/104)	5.9% (17/290)
2> to ≤3 line decrease	0.5% (1/186)	0.0% (0/104)	0.3% (1/290)
1. Based on participants with available data at baseline and one follow-up visit. Categorical variables presented as n/N (%) where N is the number of participants with available data. 2. Visual acuity measurements captured using logMAR. A 1-line improvement from baseline corresponds to a change of -0.10 logMAR.			

Adverse Events (AEs)			
AE Type	**Age 4-7 (N=186)**	**Age 8-12 (N=104)**	**Age 4-12 (N=290)**
Eye Redness	0 (0%)	1 (1%)	1 (<1%)
Headache	4 (2%)	1 (1%)	5 (2%)
Dizziness	0 (0%)	1 (1%)	1 (<1%)
Teary Eye	1 (1%)	0 (0%)	1 (<1%)
Nightmare Event	0 (0%)	1 (1%)	1 (<1%)
Overall	5 (3%)	4 (4%)	9 (3%)
Includes events reported n (rate of n/N).			

Conclusion:
As described in this 510(k) Summary, the subject and predicate devices have the same intended use and similar indications for use. There are no differences in technological characteristics between the subject and predicate devices. Clinical performance data from a real-world registry study in addition to the clinical evidence established in DEN210005 of the same device are sufficient to establish the safety and effectiveness of the subject device when used in accordance with its proposed labeling.