August 8, 2024

Luminopia, Inc.
Endri Angjeli
VP of Clinical Development
955 Massachusetts Ave #335
Cambridge, Massachusetts 02139

Re: K233720
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: July 1, 2024
Received: July 1, 2024

Dear Endri Angjeli:

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.

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)*

K233720

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 4-7, 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.

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

510(k) Owner: Luminopia, Inc.
Address: 955 Massachusetts Ave #335, Cambridge, MA 02139
Phone: 857-365-6636
Fax: 857-336-6605
Contact Person: Endri Angjeli
Date: August 8, 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 One (Submission Number: K221659)

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 4-7, 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.

Device Description:
Luminopia is Software as a Medical Device (SaMD) that is intended to improve vision in pediatric patients with amblyopia. The Luminopia SaMD consists of four software-only components: the Mobile Application, the Prescription Manager Portal, the Patient Portal, and the Backend Service Layer. The first 3 components are user-facing, while the Backend Service Layer is designed to only communicate with the other 3 components. The Luminopia SaMD is intended for prescription use only, in an at-home environment.

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.

The proposed modification is the addition of the DPVR P1 Pro HMD to the list of compatible HMDs in the Directions For Use for the Luminopia SaMD. All compatible HMDs meet the following set of minimum requirements:

Parameter	**Pico G2 4K HMD**	**Subject Device HMD (DPVR P1 Pro 4K)**
Luminance and luminance uniformity	≥ 48 cd/m^2	≥ 48 cd/m^2
Michelson contrast (low spatial frequency)	≥ 90% across field of view	≥ 90% across field of view
Michelson contrast (high spatial frequency grille pattern)	Baseline requirement	Equivalent or higher than Samsung Gear HMD across[1]
Resolution	≥ 14.0 pixels/degree (vertical) ≥ 14.4 pixels/degree (horizontal)	≥ 14.0 pixels/degree (vertical) ≥ 14.4 pixels/degree (horizontal)
IPD range support	Meets requirements ≥ 52mm IPD	Meets requirements ≥ 52mm IPD
Internet capability	Yes	Yes
Battery capacity	> 90 min	> 90 min
Weight	< 500 g (± 5%)	< 500 g (± 5%)
RF compliance	Yes	Yes

Audio support	Yes	Yes
Power button	Yes	Yes
Eye glasses compatibility	Yes	Yes
Processing capacity	> Snapdragon 821	> Snapdragon 821
Refresh rate	≥ 60 Hz	≥ 60 Hz
Field of view	≥ 51.9 degrees (horizontal) ≥ 30.6 degrees (vertical)	≥ 51.9 degrees (horizontal) ≥ 30.6 degrees (vertical)

1. The Michelson contrast is lower than 90% when tested with image analysis of a high spatial frequency grille pattern for the Pico G2 4K HMD and the Samsung Gear HMD, the current compatible HMD cleared in K221659. The DPVR P1 Pro 4K has equivalent or higher contrast than that of the Samsung Gear HMD across the field of view, at both the nominal IPD and a 52mm IPD, and therefore meets the minimum requirement.

Substantial Equivalence:

Feature	**Subject Device**	**Cleared Device (K221659)**	**Impact**
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 4-7, 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;	Luminopia One 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 One 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 One is intended for both	No change

	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.	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.	
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	- Samsung Gear HMD - Pico G2 4K	Does **not** introduce new technological characteristics or questions of safety and effectiveness
Technological Characteristics			
Device type	Software as a Medical Device (SaMD)	Software as a Medical Device (SaMD)	No change
Device design	4 software-only components: - Mobile Application - Prescription Manager Portal - Patient Portal - Backend Service Layer	4 software-only components: - Mobile Application - Prescription Manager Portal - Patient Portal - 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:	Modification of visual stimuli using:	Modification of visual stimuli using:	No change

Therapeutic mechanism	contrast reduction + dichoptic masks	contrast reduction + dichoptic masks	
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

The proposed modification is the addition of one additional head-mounted display (HMD) model to the list of compatible HMDs in the Directions For Use for the Luminopia SaMD. The intended use and Indications for Use remain the same.

No design changes for the SaMD were needed to produce compatibility for this modification, and therefore, there are no changes to the technological characteristics. Any similarities or differences in the technical specifications of the off-the-shelf HMDs are relevant only insofar as they impact one of the HMD parameters for which there are minimum requirements relevant to safety and effectiveness. Since the additional HMD meets all minimum requirements for compatibility, the proposed modification does not impact the safety and effectiveness of the SaMD.

Performance Data:
Hardware bench testing and optical testing were used to establish the compatibility of the additional HMD. The hardware testing confirmed that the additional HMD met the minimum hardware requirements for resolution, luminance, luminance uniformity, contrast, cross-talk, IPD, and non-optical parameters. Software testing validated that the Mobile Application runs as intended on the additional HMD model, and that there is proper integration between the software and the HMD. The software testing methods used were unit and integration testing, functional testing, system regression testing, negative testing, and thermal testing. All of the testing passed without deviations.

Conclusion:
The proposed modification to add one additional HMD for use with the Luminopia SaMD does not change the intended use or the technological characteristics of the predicate device. Performance testing supported this assessment, and therefore the subject and the predicate device are Substantially Equivalent.