



October 20, 2021

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

Re: DEN210005
Trade/Device Name: Luminopia One
Regulation Number: 21 CFR 886.5500
Regulation Name: Digital therapy device for amblyopia
Regulatory Class: Class II
Product Code: QQU
Dated: February 26, 2021
Received: March 1, 2021

Dear Scott Xiao:

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

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 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Luminopia One, and substantially equivalent devices of this generic type, into Class II under the generic name digital therapy device for amblyopia.

FDA identifies this generic type of device as:

Digital therapy device for amblyopia. A digital therapy device for amblyopia is a device that incorporates dichoptic presentations on visual displays through therapeutic algorithms to treat amblyopia or to improve visual acuity of patients with amblyopia.

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

On March 1, 2021, FDA received your De Novo requesting classification of the Luminopia One. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Luminopia One into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo, FDA has determined that, for the previously stated indications for use, the Luminopia One can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Adverse events due to device treatment (e.g., headache, new or worsening heterotropia, worsened vision in either eye, eye strain, eye twitching, facial redness, increased night terrors, thermal injury, dizziness, seizure, nausea, or double vision)	Clinical performance testing Labeling
Ineffective treatment leading to worsening of condition	Clinical performance testing Software verification, validation, and hazard analysis Labeling
Therapeutic effect not sustained leading to delay of treatment	Clinical performance testing Labeling
Software malfunction leading to delay of treatment	Software verification, validation, and hazard analysis Labeling

Improper use of the device including HMD or other visual display leading to ineffective treatment or adverse events	Labeling Labeling comprehension testing
Performance variations among different brands/models of visual displays leading to ineffective treatment and/or adverse events	Clinical performance testing Non-clinical performance testing Labeling Software verification, validation, and hazard analysis

In combination with the general controls of the FD&C Act, the digital therapy device for amblyopia is subject to the following special controls:

- (1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use with labeled compatible visual display devices, including evaluation of all adverse events and device performance to improve measures of visual function.
- (2) Software verification, validation, and hazard analysis must be performed. Documentation must include characterizations of the technical specifications of the software.
- (3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. All visual displays intended for use must undergo compatibility testing to ensure adequate display resolution, luminance, contrast, field of view, image quality, appropriate optical image distance, and verify their compatibility with the software and intended user (such as appropriate interpupillary distance).
- (4) Labeling must include the following:
 - (i) The minimum hardware and operating system requirements that support the software of the device;
 - (ii) The models of the visual displays validated to be compatible with this device;
 - (iii) The length of treatment and/or retreatment supported by clinical performance testing; and
 - (iv) A summary of the clinical performance testing conducted with the device.
- (5) Labeling comprehension testing with intended users must be performed.

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

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

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification

requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the digital therapy device for amblyopia they intend to market prior to marketing the device.

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

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

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

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

If you have any questions concerning the contents of the letter, please contact Elvin Ng at 240-402-4662.

Sincerely,

for Malvina B. Eydelman, M.D.

Director

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health