FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, devices for sleep apnea testing based on mandibular movement are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for devices for sleep apnea testing based on mandibular movement. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 868.2376 to subpart C to read as follows:

§ 868.2376 Device for sleep apnea testing based on mandibular movement.

(a) *Identification.* A device for sleep apnea testing based on mandibular movement is a prescription device intended to aid in evaluation of sleep apnea during sleep in patients suspected of having sleep breathing disorders by analyzing sensor readings of mandibular movement. The device is not intended as a substitute for full polysomnography nor intended to be used as an apnea monitor.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must be provided. This assessment must fulfill the following:

(i) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iii) The assessment must compare device performance with a clinical comparator device (*e.g.,* polysomnography).

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) The performance data must be provided to demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of the device.

(4) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications; and

(iii) A description of all mitigations for failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

(5) Labeling must include:

(i) A description of what the device measures and outputs to the user;

(ii) Warnings identifying sensor acquisition factors or subject conditions or characteristics (*e.g.,* conditions affecting the anatomy of the recording site, or subject conditions that may affect mandibular movement) that may impact measurement results;

(iii) Guidance for interpretation of the measurements, including a statement that the device is not intended as a substitute for full polysomnography nor intended to be used as an apnea monitor; and

(iv) The expected performance of the device for all intended use populations and environments.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07862 Filed 4–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2026–N–3928]

Medical Devices; Ophthalmic Devices; Classification of the Digital Therapy Device for Amblyopia

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the digital therapy device for amblyopia into class II (special controls). The special controls that apply to the device type are identified in this order and will be part

of the codified language for classification of the digital therapy device for amblyopia. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective April 22, 2026. The classification was applicable on October 20, 2021.

FOR FURTHER INFORMATION CONTACT: Bradley Cunningham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1414, Silver Spring, MD 20993–0002, 301–796–6484, *Bradley.Cunningham@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the digital therapy device for amblyopia into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 1, 2021, FDA received Luminopia, Inc.'s request for De Novo classification of the Luminopia One. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on October 20, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 886.5500.[1] We have named the generic type of device ''digital therapy device for amblyopia,'' and it is identified as a device that incorporates dichoptic presentations on visual displays through therapeutic algorithms to treat amblyopia or to improve visual acuity of patients with amblyopia.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES DIGITAL THERAPY DEVICE FOR AMBLYOPIA

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, and Labeling.
Ineffective treatment leading to worsening of condition	Clinical performance testing; Software verification, validation, and hazard analysis; and Labeling.
Therapeutic effect not sustained leading to delay of treatment	Clinical performance testing, and Labeling.
Software malfunction leading to delay of treatment	Software verification, validation, and hazard analysis; and Labeling.
Improper use of the device including Head-Mounted Display or other visual display leading to ineffective treatment or adverse events.	Labeling, and 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; and Software verification, validation, and hazard analysis.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) (21 U.S.C. 360(k)) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for digital therapy devices for amblyopia. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 886.5500 to subpart F to read as follows:

§ 886.5500 Digital therapy device for amblyopia.

(a) *Identification.* 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.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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