June 13, 2025

% Adam Savakus
Regulatory Consultant
Aepis Medical
6320 Mitchell Rd.
Shingle Springs, California 95682

Re: K243729
Trade/Device Name: Prismira
Regulation Number: 21 CFR 882.5803
Regulation Name: Digital therapy device for attention deficit hyperactivity disorder
Regulatory Class: Class II
Product Code: QFT
Dated: May 13, 2025
Received: May 13, 2025

Dear Adam Savakus:

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,

Jitendra V. Virani -S

For Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine 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)*

K243729

Device Name

Prismira

Indications for Use *(Describe)*

Prismira is a digital therapeutic indicated to improve attention function in adults ages 22-55 years old with primarily inattentive or combined-type Attention Deficit and Hyperactivity Disorder (ADHD). Patients who engage with Prismira demonstrate improvements in a digitally assessed measure of sustained and selective attention, Test of Variables of Attention (TOVA), and may not display benefits in typical behavioral symptoms, such as hyperactivity.

Prismira should be considered for use as part of a therapeutic program that may include clinician directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.

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

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Date Prepared:	June 15, 2025
Legal Manufacturer:	Lumos Labs Medical, a division of Lumos Labs, Inc. 16 Maiden Lane, Floor 6 San Francisco, CA 94108
Primary Contact Person:	Robert (Bob) Schafer President, Lumos Labs Medical Phone: 877-777-0502 Email: bschafer@lumoslabs.com

Regulatory Information

Device Trade Name:	Prismira
Device Classification Name:	Digital Therapeutic Software for Attention Deficit Hyperactivity Disorder
Regulation Number:	21 CFR § 882.5803
Classification Product Code:	QFT
Review Advisory Committee:	Neurology
Device Classification:	Class II
510(k) Number	K243729

Predicate Device Information

Device Manufacturer:	Akili Interactive Labs, Inc.
Submission Number:	DEN200026
Device Name:	EndeavorRx
Other Reference Devices:	EndeavorRx (K231337), EndeavorOTC (K233496)

Device Description:

Prismira is software-as-a-medical device (SaMD) that resides on the user's mobile device and can be executed at home.
Prismira is a prescription digital therapeutic indicated to improve attention function in patients 22 and older with primarily inattentive or combined type ADHD. Patients who engage with Prismira demonstrate improvements in attention functioning and may not display benefits in other behavioral symptoms such as hyperactivity. Prismira is intended to be used as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.

The Prismira App also includes an Engagement System to promote compliance with the treatment. The Engagement System gives the patient encouragement and feedback on progress at multiple timescales: performance on the most recent gameplay and historical game performance, completion of the daily assignment, progress toward the weekly target in the current week, and historical assignment completion.

Each game includes visual and optional auditory stimulus presentation. The basic input from the patient includes physical interaction with a touch screen accomplished by using the mobile device. The device's feedback within each game includes visual and optional auditory responses to the inputs. Output from each game includes a score earned by playing the game. Each gameplay is brief, typically between 1 and 5 minutes in duration, depending on the game. The treatment program guides patients through an ordered list of games (the "script") that enables subjects to engage in the recommended daily regimen (approximately 15 minutes per day).

Indications for Use:

Prismira is a digital therapeutic indicated to improve attention function in adults ages 22-55 years old with primarily inattentive or combined-type Attention Deficit and Hyperactivity Disorder (ADHD). Patients who engage with Prismira demonstrate improvements in a digitally assessed measure of sustained and selective attention, Test of Variables of Attention (TOVA), and may not display benefits in typical behavioral symptoms, such as hyperactivity.

Prismira should be considered for use as part of a therapeutic program that may include clinician directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.

Limitations

Prismira may not be appropriate for users with photo-sensitive epilepsy, color blindness, or physical limitations that restrict use of a mobile device.

Summary Comparison of Technological Characteristics

Attribute	**Subject Device: Prismira**	**Predicate Device: EndeavorRx (DEN200026)**	**Reference Device: EndeavorOTC**	**Comparison**
Manufacturer	Lumos Labs Medical	Akili Interactive Labs, Inc.	Akili Interactive Labs, Inc.	Different
Device Classification Name	Digital Therapy Device for Attention Deficit Hyperactivity Disorder	Digital Therapy Device for Attention Deficit Hyperactivity Disorder	Digital Therapy Device for Attention Deficit Hyperactivity Disorder	Same
Product Code	QFT	QFT	QFT	Same
Regulation Number	21 CFR § 882.5803	21 CFR § 882.5803	21 CFR § 882.5803	Same
Intended use	Digital therapeutic adaptive stimulus software for the closed-loop treatment of psychiatric disorders and cognitive dysfunction associated with medical conditions.	Digital therapeutic adaptive stimulus software for the closed-loop treatment of psychiatric disorders and cognitive dysfunction associated with medical conditions.	Digital therapeutic adaptive stimulus software for the closed-loop treatment of psychiatric disorders and cognitive dysfunction associated with medical conditions.	Same

Attribute	Subject Device: Prismira	Predicate Device: EndeavorRx (DEN200026)	Reference Device: EndeavorOTC	Comparison
Indication for Use	Prismira is a digital therapeutic indicated to improve attention function in adults ages 22-55 years old with primarily inattentive or combined-type Attention Deficit and Hyperactivity Disorder (ADHD). Patients who engage with Prismira demonstrate improvements in a digitally assessed measure of sustained and selective attention, Test of Variables of Attention (TOVA), and may not display benefits in typical behavioral symptoms, such as hyperactivity. Prismira should be considered for use as part of a therapeutic program that may include clinician directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.	EndeavorRx is a digital therapeutic indicated to improve attention function as measured by computer based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorRx demonstrate improvements in a digitally assessed measure Tests of Variables of Attention (TOVA) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx should be considered for use as part of a therapeutic program that may include: clinician directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.	EndeavorOTC is an over the counter digital therapeutic indicated to improve attention function as measured by computer-based testing in patients 18 and older with primarily inattentive or combined type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorOTC demonstrate improvements in a digitally assessed measure, Test of Variables of Attention (TOVA®) of sustained and selective attention and may not display benefits in typical behavioral symptoms such as hyperactivity. EndeavorOTC is not intended to be a replacement for any form of treatment and should be used as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder	Substantially equivalent Prismira is indicated for 22 years of age or older, compared to the predicate device (8-12 years). Like Prismira, the reference device, EndeavorOTC, is likewise indicated for 18 years of age and older. The difference in age range does not change the intended use of the device, and clinical testing demonstrates the subject device is safe and effective in the adult population.
System Components	Patient facing video game application Mobile device platform	Patient facing video game application Mobile device platform	Patient facing video game application Mobile device platform	Same
Proprietary Algorithm	Adaptive algorithm and Engagement System	Selective Stimulus Management Engine (SSMETM)	Selective Stimulus Management Engine (SSMETM)	Substantially Equivalent
Basic Operations	Swiping, Tapping	Steering, Tapping, Multi-tasking	Steering, Tapping, Multi-tasking	Substantially Equivalent

Attribute	Subject Device: Prismira	Predicate Device: EndeavorRx (DEN200026)	Reference Device: EndeavorOTC	Comparison
Presentation	Structured presentation of 'games' that have been designed to challenge specific cognitive domains	Structured manner across game "Challenges" and "Worlds"	Structured manner across game "Challenges" and "Worlds"	Substantially Equivalent
Mobile Platform Compatibility	iOS	iOS	iOS and Android	Same
Access	Prescription use only. Authorized and overseen by a licensed health care provider.	Prescription use only. Authorized and overseen by a licensed health care provider.	Over-the-counter use.	Same. EndeavorRx and Prismira are both prescription use only

Summary of Non-Clinical Performance Testing

Like EndeavorRx, the Prismira device software has a MODERATE level of concern. Lumos Labs Medical has developed Prismira in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued in June 2023. The technological safety and performance of the subject device have been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. The software validation activities were performed in accordance with IEC 62304 - Medical device software – Software life cycle processes. In addition, cybersecurity testing and documentation are conducted based on FDA guidance Content of Premarket Submission for Management of Cybersecurity in Medical Devices, issued in September 2023.

The results of software verification and validation testing support that Prismira functions as intended.

Summary of Clinical Performance Testing

A pivotal trial, The GAMES Study, was conducted to evaluate the safety and effectiveness of LLM-001 in adults in a randomized, double-blind, parallel-group, multi-center, sham-controlled clinical trial. Effectiveness was determined primarily by the change from baseline in the digitally assessed measure of sustained and
selective attention, the Test of Variables of Attention (TOVA®), after 9 weeks of treatment. The study enrolled 560 subjects between the ages of 22 and 55 years who were confirmed to have a diagnosis for ADHD, combined or inattentive type, as assessed using the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) and confirmed by the Mini-International Neuropsychiatric Interview (MINI) for ADHD adult version.

All 560 subjects enrolled in the GAMES Study were included in the Safety Population; 456 successfully completed the gameplay treatment and Day 63 follow-up assessments and comprised the Intent-to-Treat (ITT) Population: 224 were randomized to the LLM-001 active therapy and 232 to a control therapy. Study success was prespecified as a statistically significant difference between study groups, not a set amount of change on the TOVA-ACS within group or between groups. Results of the planned primary endpoint analysis showed that the LS mean improvement in TOVA ACS observed in the LLM-001 therapy arm was statistically significant compared to the control arm (p=0.0149). This analysis adjusts for the small percentage of TOVA ACS scores at baseline and/or follow-up that fell outside a reliable and interpretable range; it considers these points as missing and imputes them. The same analysis was performed with outlier datapoints included, and also found that the difference between the treatment arms was statistically significant (p=0.0452). Thus, these results met the prespecified study success criteria for demonstration of effectiveness in the primary endpoint. Although the LS mean improvement on the TOVA ACS in the LLM-001 therapy arm (1.09 points) was less than the recognized minimal clinically important difference (MCID) on the TOVA ACS of a 1.4 point change, the LS mean improvement was notably greater than the predicate device (0.93 point change in EndeavorRx).

[1] Steyvers, M., & Schafer, R. J. (2020). Inferring latent learning factors in large-scale cognitive training data. Nature Human Behaviour, 4(11), 1145-1155.

[2] Hardy, J. L., Nelson, R. A., Thomason, M. E., Sternberg, D. A., Katovich, K., Farzin, F., & Scanlon, M. (2015). Enhancing cognitive abilities with comprehensive training: A large, online, randomized, active-controlled trial. PLOS One, 10(9), e0134467.

[3] Osman, A. M., Madore, K. P., Jaffe, P. I., Offidani, E., Childress, A. C., Newcorn, J. H., & Schafer, R. J. (In review) Real-World Effectiveness of a Widely Available Digital Health Program in Adults with ADHD [Currently under review]

Change from Baseline in TOVA Attention Comparison Score (TOVA ACS) at Day 63
(Intent-to-Treat Population, Missing data imputed)

	Control (N = 232)	**LLM-001 (N = 224)**
Baseline		
N	232	224
Mean	-0.8	-0.9
SD	4.3	4.3
Median	0.1	-0.2
Min. to Max.	-14.6 to 6.0	-13.4 to 9.6
Day 63		
N	232	224
Mean	-0.5	0.2
SD	4.7	4.4
Median	0.2	1.3
Min. to Max.	-15.0 to 8.7	-14.0 to 7.7
Change from Baseline		
Mean	0.3	1.1
SD	3.6	3.6
Median	0.4	1.1
Min. to Max.	-11.5 to 10.9	-12.9 to 17.9
Least square model [a]		
LSM (SE)	**0.30** (0.22)	**1.09** (0.23)
LSM, 95% CI	-0.14, 0.74	0.64, 1.54
LSM Difference (SE)		**0.78** (0.32)
LSM Difference, 95% CI		0.15, 1.41
LSM Difference p-value		**0.0149**

SD = Standard Deviation; SE = Standard error; LSM = Least square means; CI = Confidence interval; Difference is computed as LLM 001 – Control
Change from Baseline is defined as the score at Day 63 minus baseline score.
[a] The linear model contains baseline score, treatment and a baseline-by-treatment interaction term

The secondary endpoint within-group (baseline to post-treatment) changes in the ADHD-RS inattentive subscale, CBS TS and SS, BRIEF-A, and WFIRS-S numerically favored LLM-001 over control; however, there were no statistically meaningful differences between groups. The analysis of the CGI-I, a global measure of clinical improvement assessed by blinded clinicians, demonstrated superior clinical benefit for the LLM-001 arm over control (p=0.0087). There were three notable exploratory responder analyses for the LLM-001 subjects: 44.2% of subjects met the TOVA ACS MCID of a 1.4 point change in their attention function on the TOVA ACS; and for the two clinician assessments, 32.1% of subjects were assessed as “very much improved” on the CGI-I, and 30.4% of subjects experienced greater than 30% reduction in their ADHD symptoms based on their ADHD-RS total score. Additionally, subjects in

the LLM-001 group demonstrated a clinically meaningful mean improvement (8.7 points on the Adult ADHD Quality of Life Questionnaire [AAQoL]) in their quality of life.

There were no serious adverse events. Only two treatment related AEs (both reports of frustration) were reported in the LLM-001 treated subjects, for an AE rate of 0.7% (2/275). No subjects exited the study early for medical or gameplay related complaints. LLM-001 treatment compliance was a mean of 874.7 minutes (97.2%) of 900 expected minutes.
The results of the pivotal clinical study demonstrate that Prismira is substantially equivalent to the predicate in terms of safety and effectiveness for its intended use in the indicated patient population.

Substantial Equivalence
The Subject Device (Prismira) has the same intended use, and similar indications for use, technological characteristics, and principles of operation as the Predicate Device (EndeavorRx, DEN200026). Moreover, Prismira complies with the same special controls as the predicate device set forth in 21 CFR § 882.5803. As demonstrated by the clinical data, the different age range and differences in software/ algorithm do not raise different questions of safety or effectiveness.

Substantial equivalence was supported by clinical and non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards (refer to the Standards Section of the eSTAR). The non-clinical testing included software testing, which verified the software implementation of the Prismira product. Clinical testing demonstrated the substantially equivalent safety and effectiveness of Prismira to the predicate device for its intended use in adults. The clinical trial results showed a statistically significant improvement in the primary effectiveness measure, TOVA, a digitally assessed measure of sustained and selective attention. Results also showed improvements in ADHD symptoms as assessed in key, clinician-assessed secondary measures ADHD-RS and CGI-I. The clinical testing also showed no new or increased safety risks in the adult patient population compared to the predicate device.
Based on the device comparison, non-clinical and clinical performance testing, the subject device does not raise any new questions of safety or effectiveness and support the substantial equivalence of the Subject and Predicate Devices.

Benefit-Risk Profile
Prismira showed a general improvement in attention associated with ADHD. The totality of the evidence demonstrated clinical benefit in attention, as measured by the TOVA in the adult population with ADHD. As noted, the risks associated with Prismira are minimal, as the treatment emergent AE rate was quite low. No serious adverse events or unanticipated adverse device effects were reported. Of the 275 subjects who received the LLM-001 therapy, only 2 (0.7%) reported treatment emergent adverse events. Both were reports of decreased frustration tolerance that resolved with conclusion of gameplay. No subjects exited the study early for medical or gameplay related complaints. Given the favorable safety profile, even small benefits in inattentive ADHD symptoms would justify use of the product.

The benefits of the Prismira device have been found to outweigh the individual risks. After evaluating all benefits, risks and applicable considerations, it has been determined that the overall residual risk of the Prismira device is acceptable, and the product is considered safe for use by the intended population.