April 4, 2025

Oculogica, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K242116
Trade/Device Name: EyeBOX EBX-4.1
Regulation Number: 21 CFR 882.1455
Regulation Name: Traumatic Brain Injury Eye Movement Assessment Aid
Regulatory Class: Class II
Product Code: QEA
Dated: July 19, 2024
Received: July 19, 2024

Dear Janice Hogan:

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,

FDA Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic 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.

510(k) Number *(if known)*
K242116

Device Name
EyeBOX

Indications for Use *(Describe)*
The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion.

A negative BOX score classification may correspond to eye movement that is consistent with a lack of concussion within one week of injury.

A positive BOX score classification corresponds to eye movement that may be present in both patients with or without a concussion within one week of injury.

The EyeBOX provides a set of eye-tracking metrics in relation to a reference database of uninjured individuals.

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

Oculogica's EyeBOX

K242116

Submitter

Oculogica Inc.
1477 S. Knowles Ave. #110F
New Richmond, WI 54017

Phone: 484-393-2694

Contact Person: Rosina Samadani, Ph.D.

Date Prepared: 4/02/2025

Name of Device: EyeBOX Model EBX-4.1

Common or Usual Name: EyeBOX

Classification Name: Neurology

Regulatory Class: Class II

Product Code: QEA

Predicate Devices

Oculogica, Inc. EyeBOX, Model EBX-4, K212310

SyncThink, Inc. EYE-SYNC, K202927

Device Description

Oculogica's EyeBOX EBX-4.1 is an eye-tracking device with custom software. The device is comprised of a host PC with integrated touchscreen interface for the operator, eye tracking camera, LCD stimulus screen and head-stabilizing rest (chin rest and forehead rest) for the patient, and data processing algorithm. The data processing algorithm detects subtle changes in eye movements resulting from concussion. The eye tracking task takes about 4 minutes to complete and involves watching a video move around the perimeter of a screen positioned in front of the patient while a high speed near-infrared (IR) camera records gaze positions 500 times per second. The post-processed data are analyzed automatically to produce one or more outcome measures.

The device contains a rechargeable battery, which makes it possible to use without a direct connection to an active power source.

The device has Wi-Fi and Ethernet capabilities, which optionally can provide the user with the ability to upload scans to a remote server, provide over-the-air software updates, and assist with customer support.

Intended Use / Indications for Use

The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion.

A negative BOX Score classification may correspond to eye movement that is consistent with a lack of concussion within one week of injury.

A positive BOX Score classification corresponds to eye movement that may be present in both patients with or without concussion within one week of injury.

The EyeBOX provides a set of eye-tracking metrics in relation to a reference database of uninjured individuals.

Summary of Technological Characteristics

- Eye-tracking is the technological principle for both the subject and predicate devices. The EyeBOX uses eye-tracking technology and a data processing algorithm to detect subtle changes in eye movements resulting from concussion. The eye tracking takes 220 seconds to complete, is non-invasive and involves watching a video move around the perimeter of an LCD monitor positioned in front of the patient while a high speed near-infrared (IR) camera records gaze positions 500 times per second. The data are analyzed automatically to produce one or more outcome measures in the form of a report. This report, in conjunction with other standard of care assessments, are used to aid in the diagnosis of concussion. A BOX score is the main diagnostic outcome measure and ranges between 0 and 20, with scores below 10 associated with lower risk of concussion and scores equal to or greater than 10 suggestive of possible concussion. The BOX Score may be used within one week of the known head injury. In addition to the BOX Score, a number of measurements are presented in relation to a normative database of uninjured individuals. The normative database allows physicians to compare ocular motor function of the patient being tested to the normal population. The measurements include pupil size and dynamics, saccades, horizontal/vertical disconjugacy, path departure from stimulus, average gaze displacement (“travel”), and blinks. The addition of more available eye tracking parameters does not raise new questions of safety or effectiveness, and the available testing demonstrates that the addition of these parameters does not adversely impact performance with respect to accuracy.

At a high level, the subject and predicate devices are based on the following same technological elements:

- The hardware for the EyeBOX Model EBX-4.0 and Model EBX 4.1 are exactly the same. This includes all components, and the form factor

- The algorithm for the BOX Score is exactly the same as the EyeBOX Model EBX-4.0

Oculogica's EyeBOX uses eye-tracking technology and a data processing algorithm to detect subtle changes in eye movements resulting from concussion. The EyeBOX principles of operation have not changed. The principles of operation are identical to its predicate device. The technological characteristics important to device function as an aid in diagnosis of concussion are not changed; the eye tracking performance and proprietary EyeBOX algorithm, which processes the eye tracking data and outputs the BOX score, are not changed.

The following technological differences exist between the subject and predicate devices:

Output report changes, including:

- Additional eye-tracking and pupillometry metrics
- Inclusion of a reference database of healthy subjects.
- Display "Not Computed" for spurious metric values

Upgrades to third party software components to remove cyber security vulnerabilities.

None of the changes in technology raise new questions of safety or effectiveness. The hardware provides the same functionality as the predicate. The inclusion of additional pupillometric metrics in the EyeBOX Model EBX-4.1 (i.e., pupil size, pupil dynamics) for contextual clinical information does not raise different questions of safety and effectiveness because both devices use multiple eye tracking parameters. Although the specific parameters measured by each device differ slightly, the fundamental principles and technological characteristics are similar, i.e., both use infrared-based eye-tracking at a high frequency and corneal reflection to measure pupil position. These differences in eye-tracking metrics are supported by performance testing based on acceptable methods that demonstrate the proposed device is as safe and effective as the predicate.

The following table presents a comparison of the device of this submission to the predicate devices.

	Primary Predicate Device K212310 (EyeBOX EBX4)	**Secondary Predicate Device K202927 (EYE-SYNC)**	**Subject Device K242116 (EyeBOX EBX 4.1)**
Trade Name	EyeBOX EBX4	EYE-SYNC	EyeBOX EBX 4.1
Manufacturer	Oculogica, Inc.	SyncThink (now NeuroSync)	Oculogica, Inc.
Model	EBX-4 (Oculogica P/N: DMR-0004)	EYE-SYNC	EBX-4.1
Product Code and Regulation	QEA 21 CFR 882.1455 Traumatic brain injury eye movement assessment aid	QEA 21 CFR 882.1455 Traumatic brain injury eye movement assessment aid	QEA 21 CFR 882.1455 Traumatic brain injury eye movement assessment aid

	Primary Predicate Device K212310 (EyeBOX EBX4)	**Secondary Predicate Device K202927 (EYE-SYNC)**	**Subject Device K242116 (EyeBOX EBX 4.1)**
Indications for Use	The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion.	The EYE-SYNC® is intended for recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects. The EYE-SYNC® is intended to record, measure, and analyze eye movements as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), within three days of sport-related head injury in patients 17-24 years of age in conjunction with a standard neurological assessment, for use by medical professionals qualified to interpret the results of a concussion assessment examination. A negative EYE-SYNC® classification corresponds to eye movements that are consistent with a lack of concussion. A positive EYE-SYNC® classification corresponds to eye movements that may be present in patients with concussion. *The EYE-SYNC output report shows results in comparison to a normative database.*	The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative BOX Score classification may correspond to eye movement that is consistent with a lack of concussion within one week of injury. A positive BOX Score classification corresponds to eye movement that may be present in patients with concussion within one week of injury. The EyeBOX provides a set of eye-tracking metrics in relation to a reference database of uninjured individuals.
User Population	Patients 5 through 67 years of age	No age range specified for visual tracking impairment.	Patients 5 through 67 years of age

	Primary Predicate Device K212310 (EyeBOX EBX4)	**Secondary Predicate Device K202927 (EYE-SYNC)**	**Subject Device K242116 (EyeBOX EBX 4.1)**
		Ages 17 – 24 years for concussion	
Device Description	Oculogica's EyeBOX is an eye-tracking device with custom software. The device is comprised of a host PC with integrated touchscreen interface for the operator and patient stimulus, eye tracking camera, and separate head-stabilizing rest for the patient, and data processing algorithm. The data processing algorithm detects subtle changes in eye movements resulting from concussion. The eye tracking task takes about 4 minutes to complete and involves watching a video move around the perimeter of an LCD monitor positioned in front of the patient while a high speed infrared (IR) camera records gaze positions 500 times per second. The post-processed data are analyzed automatically to produce one or more outcome measures.	SyncThink's EYE-SYNCTM consists of two components. These components are provided as a system with preloaded software. The EYE-SYNC is a fully-integrated, head-mounted eye-tracking system with two primary system components: 1) the head mounted display, containing the eye-tracking hardware and software system; and, 2) an integrated handheld peripheral used to administer the test and store testing results. The eye tracking unit includes two high-speed infrared cameras connected to a dedicated image analysis computing system. Camera lighting is provided by 12 high quality Light-emitting Diodes (LEDs) centered at 850 nanometers. EYE-SYNC is a less than one minute, non-invasive eye-tracking test that provides a quantitative representation of attention using precise measurements of eye gaze position relative to a target stimulus. Eye gaze tracking is performed using a proprietary implementation of the pupil-corneal reaction method. Display and eye tracking are controlled using the attached Windows-based handheld. Batteries provide power for	Oculogica's EyeBOX is an eye-tracking device with custom software. The device is comprised of a host PC with integrated touchscreen interface for the operator and patient stimulus, eye tracking camera, and separate head-stabilizing rest for the patient, and data processing algorithm. The data processing algorithm detects subtle changes in eye movements resulting from concussion. The eye tracking task takes about 4 minutes to complete and involves watching a video move around the perimeter of an LCD monitor positioned in front of the patient while a high speed infrared (IR) camera records gaze positions 500 times per second. The post-processed data are analyzed automatically to produce one or more outcome measures.

	Primary Predicate Device K212310 (EyeBOX EBX4)	Secondary Predicate Device K202927 (EYE-SYNC)	Subject Device K242116 (EyeBOX EBX 4.1)
		remote use (away from power source). As a subject tracks a predictable moving target that follows a circular trajectory on a screen within the head mounted system, eye gaze position and time stamp are recorded by the use of cameras in the head mounted system. Multiple eye gaze positions relative to the target stimulus are measured and analyzed for position error variability using installed software, and the results are displayed and stored on the handheld peripheral	
Accessories	External power supply with power cord	External power supply with power cord	External power supply with power cord
Dimensions (l x w x h)	18.7in (H) x 11.6in (W) x 7.8in (D)	Headset	18.7in (H) x 11.6in (W) x 7.8in (D)
Weight	12 lb.	None specified	12 lb.
Power Source	18V DC, 65W, internal rechargeable battery	Internal battery	18V DC, 65W, internal rechargeable battery
Biocompatibility	None claimed	None specified	None claimed
Software	EyeBOX 4.0	None specified	EyeBOX 4.13.16
Sterilization	Not required	Non-sterile	Not required
Standards with which the Device Complies	Provided in the K212310 and K242116 Submissions	EN62471 Photobiological Safety of Lamps and Lamp Systems	Provided in the K212310 and K242116 Submissions
WiFi Functionality	Provided	None specified	Provided
Enclosure	Table-top	Goggles	Table-top

	Primary Predicate Device K212310 (EyeBOX EBX4)	**Secondary Predicate Device K202927 (EYE-SYNC)**	**Subject Device K242116 (EyeBOX EBX 4.1)**
Patient position	Seated only	None specified	Seated only
Normative database reporting	Special controls provide for a reference database in K212310	None specified	Reference database provided for in the special controls for K212310 EyeBOX Model EBX-4 Metrics are measured using the same technology and process as K202927
Tissue Contact	None. Patient is not intended to touch the device.	Goggles	None. Patient is not intended to touch the device.
Head stabilization	External chin rest	None needed	External chin rest
Length of test	220 seconds	Less than 1 minute	220 seconds
Eye-tracking region of interest	Dynamic region of interest moves during test	Virtually presented region of interest	Dynamic region of interest moves during test
Eye-tracking Speed	500 fps	60 Hz	500 fps
IR Illuminator Size	5x5 grid of LED's	12 LEDs	5x5 grid of LED's
IR Illumination wavelength	850 nm	850 nm	850 nm
IR Illumination and Camera Placement	Below stimulus screen	Around edges of stimulus screen	Below stimulus screen
IR light filter	IR-passing acrylic	None specified	IR-passing acrylic
Blink Removal	400ms before and after detected blinks	None specified	400ms before and after detected blinks
Gaze Normalization	Automatic	None specified	Automatic
Diagnostic Algorithm	BOX score	Negative or Positive classification	BOX score
Eye-tracking precision / Spatial Resolution	0.016 +/- 0.001 degrees RMS	None specified	0.016 +/- 0.001 degrees RMS

	Primary Predicate Device K212310 (EyeBOX EBX4)	**Secondary Predicate Device K202927 (EYE-SYNC)**	**Subject Device K242116 (EyeBOX EBX 4.1)**
Eye-tracking Step Response	3 frames at 500fps	60 Hz	3 frames at 500fps
Eye-tracking pre-processing	For BOX Score: Blink removal, normalization using variance, noise filtering Normative Database: Blink removal, normalization using variance, noise filtering	None specified	For BOX Score: K212310 EyeBOX Model EBX-4 Normative Database: Blink removal, normalization using segment medians, noise filtering, pupil size conversion
Scan Quality Criteria	>30% usable data	None specified	>40% usable data and <=5% data removed due to gaze failures, and no missing segments
Operator Interface	Touchscreen	None specified	Touchscreen
Patient Stimulus	Combined with operator interface screen	Within V/R Goggle headset	Combined with operator interface screen
Stimulus Size	174mm ± 2mm (H) x 218mm ± 2mm (W)	None specified	174mm ± 2mm (H) x 218mm ± 2mm (W)
Computer	Internal Windows-based computer	Android tablet	Internal Windows-based computer
Distance from screen to patient's eyes	38-42 cm	None specified	38-42 cm
Distance from camera to patient's eyes	45-50 cm	None specified	45-50 cm
Camera angle to patients face	20 ± 2 degrees	None specified	20 ± 2 degrees
Eye-tracking Metrics	N/A	• Smooth Pursuit • Saccades • VOR • VOR cancellation	• Horizontal/Vertical Disconjugacy • Path Departure from Stimulus • Average Gaze Displacement ("Travel") • Saccades

	Primary Predicate Device K212310 (EyeBOX EBX4)	Secondary Predicate Device K202927 (EYE-SYNC)	Subject Device K242116 (EyeBOX EBX 4.1)
			• Pupil size and dynamics • Blinks

Performance Data

The following verification / validation activities were performed. Results of this testing demonstrates these changes do not adversely impact device performance.

- Software verification
- User acceptance testing
- Normative database testing
- Output Report Metric Selection for Concussion

Additional Eye-tracking Metrics Performance Testing

The following eye-tracking metrics are included in the EyeBOX report:

- Pupil Size (Pupil Size, Pupil Size Dynamics, Dilation Speed, Dilation Speed Variance, Constriction Speed Variance)
- Blinks (Blink Rate, Blink Duration)
- Horizontal/Vertical Disconjugacy
- Path Departure from Stimulus
- Average Gaze Displacement (“Travel”)
- Saccades (Saccade Rate, Saccade Peak Velocity Variance)

These metrics are provided for contextual clinical information and are not intended to aid in diagnosis.

To support the inclusion of these additional eye metrics, accuracy and precision testing was completed for eye-tracking measurements including timestamp, gaze position, pupil size (diameter), and blink duration. Accuracy testing was also conducted for blink count and saccade detection.

Reliability of EyeBOX eye-tracking metrics was evaluated through test-retest performance testing using a study of 30 healthy individuals from the EyeBOX normative database. Each participant completed two EyeBOX assessments using identical stimulus videos, with the second test conducted shortly after the first test.

The expected variation between repeated tests was expressed using Bland-Altman 95% limits of agreement (LoA). The expected variation range for each metric is incorporated in the device output. In all instances, the EyeBOX Model EBX-4.1 functioned as intended.

Conclusion

The EyeBOX Model EBX-4.1 has the same intended use and principle of operation as the previously cleared EyeBOX Model EBX-4. In addition, the EyeBOX Model EBX-4.1 device has similar technological characteristics as its predicates. None of the changes in technology raise new questions of safety or effectiveness, and comprehensive testing demonstrates that these changes also do not adversely impact performance. Thus, the EyeBOX Model EBX-4.1 device is substantially equivalent to its predicate devices.