June 5, 2026

Oculogica, Inc.
% Janice Hogan
Partner
Hogan Lovells
1735 Market St., Suite 2300
Philadelphia, Pennsylvania 19103

Re: K254086
Trade/Device Name: EyeBOX SNAP
Regulation Number: 21 CFR 882.1455
Regulation Name: Traumatic brain injury eye movement assessment aid
Regulatory Class: Class II
Product Code: QEA
Dated: May 6, 2026
Received: May 6, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JAY R. GUPTA -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254086

Please provide the device trade name(s).

EyeBOX SNAP

Please provide your Indications for Use below.

EyeBOX SNAP provides a multi-modal measure (SNAP Score) to aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), in patients 15 through 25 years of age, in conjunction with a clinical assessment.

A negative SNAP Score classification corresponds to eye movements and symptom severity that are consistent with a lack of concussion within 3 days of injury.

A positive SNAP Score classification corresponds to eye movements and symptom severity that may be present in patients with concussion within 3 days of injury.

EyeBOX SNAP provides a set of eye-tracking metrics in relation to a reference database of uninjured individuals. These metrics can be used at any time.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Oculogica's EyeBOX SNAP

Submitter

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

Phone: 484-393-2694

Contact Person: Rosina Samadani, Ph.D.

Date Prepared: December 17, 2025

Name of Device: EyeBOX SNAP

Common or Usual Name: EyeBOX SNAP

Classification Name: Neurology

Regulatory Class: Class II

Product Code: QEA

Predicate Device: Oculogica, Inc. EyeBOX, Model EBX-4.1, K242116

Device Description

Oculogica's EyeBOX SNAP is an eye-tracking device with custom software. The device is comprised of a handheld device, a touchscreen interface, an integrated eye tracking camera, a stimulus screen/display, two speakers for stimulus audio, and a data processing algorithm. The data processing algorithm detects subtle changes in eye movements resulting from concussion. The eye tracking task takes 90 seconds 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 167 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 capabilities, which optionally provides the user 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

EyeBOX SNAP provides a multi-modal measure (SNAP Score) to aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), in patients 15 through 25 years of age, in conjunction with a clinical assessment.

A negative SNAP Score classification corresponds to eye movements and symptom severity that are consistent with a lack of concussion within 3 days of injury.

A positive SNAP Score classification corresponds to eye movements and symptom severity that may be present in patients with concussion within 3 days of injury.

EyeBOX SNAP provides a set of eye-tracking metrics in relation to a reference database of uninjured individuals. These metrics can be used at any time.

Summary of Technological Characteristics

Eye-tracking is the technological principle for both the subject and predicate devices. The EyeBOX SNAP uses eye-tracking technology and a data processing algorithm to detect subtle changes in eye movements resulting from concussion. The eye tracking takes 90 seconds to complete, is non-invasive and involves watching a video move around the perimeter of an LCD screen in front of the patient while a high speed near-infrared (IR) camera records gaze positions 167 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, is used to aid in the diagnosis of concussion. A SNAP score is the main diagnostic outcome measure and ranges between 0 and 20, with scores below 10 associated with lack of concussion and scores equal to or greater than 10 with concussion. In addition to the SNAP Score, a number of measurements are presented in relation to a normative database of uninjured individuals and a database of concussed 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, visual tracking, blinks, and saccades.

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

- EyeBOX SNAP uses eye-tracking technology and a proprietary data processing algorithm to detect subtle changes in eye movements resulting from concussion, thus the principles of operation are identical to its predicate device.

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

- The form factor has changed from the previous desktop configuration to a handheld unit that is held up to the patient's face.
- The eye-tracking camera operates at 167 Hz vs. the predicate device which operates at 500 Hz.
- The eye-tracking component of the test is 90 seconds vs. the predicate device which has a test duration of 210 seconds.

- The primary outcome score algorithm has been modified to enhance the accuracy of the adjunctive information while maintaining the same level of physician involvement in final diagnostic determination as the predicate device.

None of the changes in technology raise new questions of safety or effectiveness. The hardware provides the same functionality as the predicate and the change in form factor does not introduce new risks. Similarly, the algorithm modification solely enhanced the device performance and does not alter the use of the device. Therefore, the safety and effectiveness of the final device is the same as the predicate.

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

	Predicate Device	Subject Device
510(k) Number	K242116	TBD
Trade Name	EyeBOX	EyeBOX SNAP
Manufacturer	Oculogica, Inc.	Same
Model	EBX-4.1	EyeBOX SNAP
Product Code	QEA	Same
Regulation	21 CFR 882.1455 Traumatic brain injury eye movement assessment aid	Same
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 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.	EyeBOX SNAP provides a multi-modal measure (SNAP Score) to aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), in patients 15 through 25 years of age, in conjunction with a clinical assessment. A negative SNAP Score classification corresponds to eye movements and symptom severity that are consistent with a lack of concussion within 3 days of injury. A positive SNAP Score classification corresponds to eye movements and symptom severity that may be present in patients with concussion within 3 days of injury. EyeBOX SNAP provides a set of eye-tracking metrics in relation to a reference database of uninjured

	Predicate Device	Subject Device
		individuals. These metrics can be used at any time.
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 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.	Oculogica's EyeBOX SNAP is an eye-tracking device with custom software. The device is comprised of a handheld device, a touchscreen interface, an integrated eye tracking camera, a stimulus screen/display, and two speakers for stimulus audio, and data processing algorithm. The data processing algorithm detects subtle changes in eye movements resulting from concussion. The eye tracking task takes 90 seconds 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 167 times per second. The post-processed data are analyzed automatically to produce one or more outcome measures.
Performance Testing – Clinical	80.4% sensitivity (66.1%, 91.9%) 66.1% specificity (59.7%, 72.1%) 31.6% PPV (23.3%, 40.9%) 94.5% NPV (89.9%, 97.5%)	89.6% sensitivity (80.6%, 95.1%) 93.6% specificity (90.2%, 96.1%) 43.0% PPV (32.3,% 56.9) 99.4% NPV (99.0%, 99.8%)
Accessories	External power supply with power cord, storage/transport case	Same
Dimensions (l x w x h)	18.7in (H) x 11.6in (W) x 7.8in (D)	21cm (W) x 8.5 cm (H) x 25cm (D)

	Predicate Device	Subject Device
Weight	12 lbs.	2.7 lbs.
Power Source	18V DC 65W power supply, internal rechargeable battery	5V DC 12W power supply, internal rechargeable battery
Sterilization	Not required	Non-sterile
WiFi Functionality	Provided	Same
Enclosure	Table-top	Binocular-like frame
Patient position	Seated	Same
Patient-Contacting Materials	None. Patient is not intended to touch the device.	Silicone eye-piece. Sides, top, and bottom accessible.
Head stabilization	External chin rest	None needed
Length of test	210 seconds; comprised of 10-seconds of pre-roll, and five 40-second eye-tracking cycles	90 seconds; comprised of 10 seconds of pre-roll, and two 40-second eye-tracking cycles
Eye-tracking Speed	500 fps	167 fps
IR Illuminator Size	5x5 grid of LED's	4 LEDs
IR Illumination wavelength	850 nm	850 nm
IR Illumination and Camera Placement	Below stimulus screen	Illuminators: Sides of eyes Camera: Below stimulus screen
IR light filter	IR-passing acrylic	Same
Diagnostic Algorithm	BOX Score, comprised of eye-tracking metrics	SNAP Score, comprised of eye-tracking metrics and symptom information
Eye-tracking pre-processing	Blink removal, normalization, noise filtering	Same
Scan Quality Criteria	>40% usable data	Same
Computer	Internal Windows-based computer	Internal ARM-based computer
Operator Interface	Touchscreen	Same
Patient Stimulus	LCD screen	Same
Stimulus Size	174mm ± 2mm (H) x 218mm ± 2mm (W)	45.36 mm± 1mm (H) x 56.7mm ± 1mm (W)
Stimulus Magnification Lens	None	200mm Focal Length
Distance from screen to patient's eyes	38-42 cm	108 mm ± 5mm screen to magnifying lens, 30-50 mm lens to eye
Camera angle to patients face	20 ± 2 degrees	12 ± 2 degrees
Normative Reference Database	• Pupil size and dynamics • Saccades • Visual tracking • Blinks	Same

Performance Data

Biocompatibility, EMC and Software Verification and Validation testing were performed. In all instances, the EyeBOX SNAP functioned as intended.

The SNAP Score was developed based on a development set of data collected on concussed individuals and healthy controls. This algorithm was trained and then validated on a population of concussed and non-injured individuals that were not part of the algorithm development set.

The full SNAP Score report, accessible via a cloud portal, presents metrics relative to a normative database to provide a diagnostic reference. The normative database was established using a cohort of n=1,000 participants that had no history of head injury within the last year and met the inclusion and exclusion criteria for an EyeBOX SNAP scan.

Additional Eye-tracking Metrics Performance Testing

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

- Pupil Size (Pupil Size, Pupil Size Dynamics, 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.

Clinical Testing

The clinical study recruited concussed participants ages 17-24 years (mean 19.0, SD 1.1) from three sites in the US. Eye movements and symptoms severity were collected from uninjured individuals during arrival and from concussed individuals within 72 hours of injury and at recovery from concussion. Eye movements were measured while participants viewed a 90-second video moving around the periphery of a display. Size and position of pupils were recorded at 167 Hz with an infrared eye-tracker. Participants rated severity of symptoms in the same clinical visit during which eye movements were measured. For regression, eye movements were expressed as one composite predictor, and measurements of symptoms were expressed as a second predictor, both in standardized units.

A validation dataset demonstrated EyeBOX SNAP to be a robust indicator of concussion with 89.6% sensitivity, 93.6% specificity, 43.0% PPV, and 99.4% NPV.

Conclusion

The EyeBOX SNAP has the same intended use and principles of operation as the previously cleared EyeBOX Model EBX-4.1. In addition, the EyeBOX SNAP has similar technological characteristics as its predicate. 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 SNAP is substantially equivalent to its predicate device.