December 22, 2021

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

Re: K212310
Trade/Device Name: EyeBOX (Model EBX-4)
Regulation Number: 21 CFR 882.1455
Regulation Name: Traumatic Brain Injury Eye Movement Assessment Aid
Regulatory Class: Class II
Product Code: QEA
Dated: November 29, 2021
Received: November 29, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*

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), 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.

Type of Use *(Select one or both, as applicable)*

x 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 Model EBX-4

Date Prepared:	11/19/2021
Submitted by:	Oculogica Inc. 33 IRVING PLACE NEW YORK, NY 10003 ROSINA SAMADANI, PH.D. 484-393-2694
Subject Device Name:	EyeBOX Model EBX-4
Predicate Device Name:	Oculogica, Inc. EyeBOX, Model OCL 02.5, K201841
Regulation Number:	21 CFR 882.1455
Regulation Name:	Traumatic brain injury eye movement assessment aid
Regulatory Class:	Class II
Product Code:	QEA
Review Panel:	Neurology
Manufacturer:	Oculogica Inc. 33 IRVING PLACE NEW YORK, NY 10003
Registration Number:	301453677
Manufacturer Contact:	ROSINA SAMADANI, PH.D. 484-393-2694 ROSINA@OCULOGICA.COM

Intended Use / Indications for Use

The EyeBOX is intended to be used as an aid in diagnosis of concussion.

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.

Device Description

Oculogica's EyeBOX model EBX-4 uses eye-tracking technology and a data processing algorithm to detect 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, positioned just below the screen, records eye movements. The data are then analyzed to produce one or more outcome measures.

The patient sits in front of the device with their head secured in a chinrest about 40 cm from the middle of the display. A face tracking camera, positioned above the screen, assists the patient and operator with proper placement of the patient by providing a second set of eye coordinates in three-dimensional space to calculate the patient's distance from the screen and the patient face's position relative to the display.

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 send reports to a remote printer and/or file storage location.

Technological Characteristics

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 modifications have been implemented compared to the predicate.

- The integrated headrest and chinrest have been removed.
- The eye tracking camera is replaced with a camera system having equivalent function.
- Electronic components have been replaced to accommodate form factor changes.
- Minor changes have been made to the user interface to simplify user interaction.
- Minor changes have been made to the EyeBOX report to assist interpretation of results.

None of the changes in technology raise new questions of safety or effectiveness. The hardware provides the same functionality as the predicate. 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	K201841	K212310
Trade Name	EyeBOX	Same
Model	OCL 02.5	EBX-4 / DMR-0004
Manufacturer	Oculogica, Inc.	Same
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), 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.	Same

	Predicate Device	Subject Device
	A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion.	
Overall form factor	The predicate device (OCL 02.5) has two ends, one for the patient and one for the operator. The patient end contains a chinrest and a dedicated screen is used to display the video stimulus to the patient. A moveable operator console is used by the technician to control the device and enter data. The device's dimensions are approximately 21" x 20" x 26" (h, w, d) and it weighs about 34 pounds. Since it does not have an internal battery, it must be connected to A/C power.	The EBX-4 is similar in shape to an all-in-one PC but without a keyboard. The screen is mounted on a pedestal that can be tilted up or down. The device's dimensions are approximately 19" x 12" x 8" (h, w, d) and it weighs about 12 pounds. A separate chinrest must be used with the device. Because it includes a rechargeable battery, it can be used with or without a connection to A/C power.
Biocompatibility	The patient's head is stabilized by the chinrest and headrest. The user manual instructs that an appropriate drape be used to avoid direct patient contact, so no biocompatibility is claimed.	There is no patient contact with the EyeBOX EBX-4, so no biocompatibility is claimed.
Eye tracking	An IR machine vision camera operates at 500 fps and calculates gaze coordinates from the image data. 3-frame smoothing (filtering) is used to remove high frequency noise. No head movement compensation is employed. The eye-tracking system has a spatial resolution of < 0.01°.	Same
Patient positioning	Seated only. A fixed headrest/chinrest assembly is used to position the patient's head at the correct position from the camera.	Seated only, cameras are used to calculate the distance between the display and the patient's eyes to establish the correct position for the patient and chinrest.
Computer and other electronics	Contains a general-purpose computer, two LCD screens (1 for the stimulus display and 1 for the operator console), an infrared light illuminator, machine vision camera, and related power components.	Similar. The device uses a single LCD touchscreen, two cameras, and a chargeable battery.
Principle of Operation	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	Same

	Predicate Device	Subject Device
	(IR) camera records gaze positions 500 times per second. The post-processed data are analyzed automatically to produce a BOX score.	
WiFi Functionality	Provided	Same
Enclosure	Table-top	Same

Summary of Clinical Testing

No new clinical data were collected.

Summary of Performance Testing

The following verification / validation activities were performed subsequent to a risk assessment evaluation of the device modifications per the Oculogica Quality Management System. Results of this comprehensive testing demonstrates these changes do not adversely impact device performance.

- Electromagnetic emissions, immunity, and safety testing according to IEC 60601-1-2:2014 (4TH EDITION) *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- Hardware verification testing
- Hardware specification testing
- Eye-tracking functional testing
- Eye-tracking bench testing
- Software verification
- User acceptance testing
- Light hazard testing for ophthalmic devices

In all instances, the EyeBOX Model EBX-4 functioned as intended.

Substantial Equivalence

The EyeBOX Model EBX-4 is as safe and effective as the EyeBOX Model OCL 02.5. The EyeBOX Model EBX-4 has the same indication for use and similar technological characteristics, and principles of operation as its predicate device. Performance data demonstrate that the EyeBOX Model EBX-4 is as safe and effective as EyeBOX Model OCL 02.5. Therefore, the minor technological differences between the EyeBOX Model EBX-4 and its predicate device raise no new issues of safety or effectiveness. Thus, the EyeBOX Model EBX-4 is substantially equivalent.

Conclusions

The EyeBOX Model EBX-4 has the same intended use and principle of operation as the previously cleared EyeBOX Model OCL 02.5 device. In addition, the EyeBOX Model EBX-4 device 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 Model EBX-4 device is substantially equivalent to its predicate device.