September 6, 2020

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

Re: K201841
Trade/Device Name: EyeBOX
Regulation Number: 21 CFR 882.1455
Regulation Name: Traumatic brain injury eye movement assessment aid
Regulatory Class: Class II
Product Code: QEA
Dated: July 2, 2020
Received: July 2, 2020

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,

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: 06/30/2020
See PRA Statement below.

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)*

☒ 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 [21 CFR 807.92]

Date Prepared:	9/4/2020
Submission Number:	K201841
Submitted by:	Oculogica Inc. 33 IRVING PLACE NEW YORK, NY 10003 ROSINA SAMADANI, PH.D. 484-393-2694
Subject Device Name:	**EyeBOX, Model OCL 02.5**
Predicate Device Name:	**EyeBOX, Model OCL 02, K191183**
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

The company's EyeBOX Model OCL 02.5 device is a modification to the EyeBOX Model OCL 02 device, which was cleared under premarket notification K191183. The EyeBOX Model OCL 02.5 device has the same intended use, the same principles of operation, and similar technological characteristics as the previously cleared EyeBOX Model OCL 02 device. None of the changes in technology raise new questions of safety or effectiveness, and comprehensive testing demonstrates that these changes do not adversely impact performance.

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

	Predicate Device	**Subject Device**
510(k) Number	K191183	K201841
Trade Name	EyeBOX	Same
Model Number	OCL 02	OCL 02.5
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. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion.	Same
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, 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 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.	Same
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 (IR) camera records gaze positions 500 times per second. The post-processed data are analyzed automatically to produce a BOX score.	Same
WiFi Functionality	Provided	Same
Enclosure	Table-top	Same

Patient position	Seated only	Same

1. Intended Use and Indications for Use Statement

No change is made to the intended use of the device, the patient population or intended user.

> 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.

2. 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 changes have been implemented.

- The eye tracking camera is replaced with a camera system having equivalent function.
- Certain components are replaced with components having equivalent function.
- Minor changes to the user interface to simplify user interaction.
- Minor changes to the EyeBOX report to assist interpretation of results.

None of the changes in technology raise new questions of safety or effectiveness.

3. Performance Testing

The following verification / validation activities were performed as required by the risk assessment of the changes according to the Oculogica Quality Management System. Results of this comprehensive testing demonstrate that these changes also do not adversely impact performance.

- Electromagnetic emissions and immunity 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*
- Z80.36-2016 - Light Hazard Protection For Ophthalmic Instruments
- Bench testing was performed on an artificial eye (designed with similar geometry to a human eye) to demonstrate that the spatial precision and step response of the new camera met performance requirements.
- Testing was performed in N=84 human participants to demonstrate that the new camera and analysis could reliably detect blinks and gaze position across the range of gaze positions measured by the device.

- Software verification and user testing

4. Conclusion

The EyeBOX Model OCL 02.5 device has the same intended use and principle of operation as the previously cleared EyeBOX Model OCL 02 device. In addition, the EyeBOX Model OCL 02.5 device has comparable 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 do not adversely impact performance. Thus, the EyeBOX Model OCL 02 device is substantially equivalent to its predicate device.