



July 31, 2019

Oculogica, Inc.
Rosina Samadani
CEO
33 Irving Place
New York, New York 10003

Re: K191183

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: May 2, 2019
Received: May 2, 2019

Dear Rosina Samadani:

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

Indications for Use

510(k) Number (if known)

K191183

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: July 29, 2019
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**
Predicate Device Name: **EyeBOX, Model OCL 01, DEN170091**
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: Pending
Manufacturer Contact: ROSINA SAMADANI, PH.D.
484-393-2694
ROSINA@OCULOGICA.COM

The company's EyeBOX Model OCL 02 device is a modification to the EyeBOX Model OCL 01 device, which was granted marketing authorization under De Novo request DEN170091 in December 2018. The EyeBOX Model OCL 02 device has the same intended use, the same principles of operation, and similar technological characteristics as the previously cleared EyeBOX Model OCL 01 device. Thus, the EyeBOX Model OCL 02 device is substantially equivalent to its predicate.

The following table presents a comparison of the device of this submission to the device granted marketing authorization under DEN170091.

	Predicate Device	Subject Device
510(k) Number	DEN170091	TBD
Trade Name	EyeBOX	Same
Model Number	OCL 01	OCL 02
Manufacturer	Oculogica, Inc.	Same
Product Code	QEA	Same
Regulation	21 CFR 882.1455 Traumatic brain injury eye movement assessment aid	Same

Indications for Use	<p>The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion.</p> <p>A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion.</p> <p>A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion.</p>	<p>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.</p> <p>A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion.</p> <p>A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion.</p>
Device Description	<p>Ocologica’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.</p>	Same
Principle of operation	<p>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.</p>	Same
WiFi Functionality	None	Provided
Enclosure	Wheeled Chassis	Table-top
Patient position	Seated and recumbent	Seated only

Intended Use and Indications for Use Statement

No change is made to the intended use of the device. The company proposes to modify the Indications for Use statement to recognize that mild traumatic brain injury (mTBI) is used interchangeably with concussion in clinical practice and the medical literature. This does not change the intended use population. The proposed wording of the Indications for Use statement is provided below. The phrase “, ***also known as mild traumatic brain injury (mTBI)***,” (shown in italicized and bolded text for ease of review only) has been added; no wording is deleted.

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.

Although this results in a minor modification to the Indications for Use wording, it does not alter the intended diagnostic effect of the device.

Technological Characteristics

The technological characteristics of the EyeBOX Model OCL 02 device are very similar to that of the EyeBOX Model OCL 01 authorized under DEN170091. The principles of operation are not changed. The technological characteristics which are important to device function as an aid in diagnosis of concussion are not changed; these include the following characteristics:

- The principles of operation are not changed;
- The eye tracking camera is not changed;
- The optical path is not changed;
- The EyeBOX algorithm which processes the eye tracking data and outputs the BOX score is not changed;

Thus, the device is identical to that of DEN170091 in all aspects important to its use as an aid in diagnosis of concussion. The following changes have been implemented but do not affect the safety and effectiveness of the EyeBOX device.

- Change from a wheeled chassis to a tabletop model
- Change to use with seated patients only
- Provide WiFi functionality
- Software changes to allow for licensing of device use.

Performance Testing

The following verification / validation activities were performed as required by the risk assessment of the changes according to the same well-established methods and procedures presented in DEN170091.

- Safety testing according to ANSI/AAMI ES60601-1: 2005 / A1:2012 *Medical electrical equipment - Part 1: General requirements for basic safety and essential 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*
- Hardware verification
- Software validation

Conclusion

the EyeBOX Model OCL 02 device has the same intended use and principle of operation as the previously authorized EyeBOX Model OCL 01 device. In addition, the EyeBOX Model OCL 02 device has very similar indications and technological characteristics as its predicate. Although there are minor differences between the EyeBOX Model OCL 02 device and its predicate devices, those differences do not raise new questions of safety or effectiveness and nonclinical testing demonstrates the device function is equivalent to the legally marketed predicate device. Thus, the EyeBOX Model OCL 02 device is substantially equivalent.