



December 28, 2018

Ocologica, Inc.  
% Janice Hogan  
Regulatory Counsel  
Hogan Lovells US LLP  
1735 Market Street, 23rd Floor  
Philadelphia, Pennsylvania 19103

Re: DEN170091

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: December 22, 2017  
Received: December 22, 2017

Dear Janice Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the EyeBOX, a prescription device under 21 CFR Part 801.109 with the following indications for use:

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.

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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the EyeBOX, and substantially equivalent devices of this generic type, into Class II under the generic name traumatic brain injury eye movement assessment aid.

FDA identifies this generic type of device as:

**Traumatic brain injury eye movement assessment aid.** A traumatic brain injury eye movement assessment aid is a prescription device that uses a patient's tracked eye movements to provide an

interpretation of the functional condition of the patient's brain. This device is an assessment aid that is not intended for standalone detection or diagnostic purposes.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 22, 2017, FDA received your De Novo requesting classification of the EyeBOX. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the EyeBOX into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the EyeBOX can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Incorrect or misinterpreted results, including: <ul style="list-style-type: none"> <li>• False positive: brain injury when in fact none is present</li> <li>• False negative: no brain injury when in fact brain injury is present</li> </ul>	Clinical performance testing; Software verification, validation, and hazard analysis; and Labeling
Interference with other devices	Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis
Electrical shock or burn	Electrical safety testing Software verification, validation, and hazard analysis
Adverse tissue reaction	Biocompatibility evaluation
Eye hazard or injury	Light hazard assessment

In combination with the general controls of the FD&C Act, the traumatic brain injury eye movement assessment aid is subject to the following special controls:

- (1) Clinical performance data under anticipated conditions of use must evaluate tracked eye movement in supporting the indications for use and include the following:
  - (i) Evaluation of sensitivity, specificity, positive predictive value, and negative predictive value using a reference method of diagnosis;
  - (ii) Evaluation of device test-retest reliability; and
  - (iii) A description of the development of the reference method of diagnosis, which may include a normative database, to include the following:
    - (A) A discussion of how the clinical work-up was completed to establish the reference method of diagnosis, including the establishment of inclusion and exclusion criteria; and
    - (B) If using a normative database, a description of how the “normal” population was established, and the statistical methods and model assumptions used.
- (2) Software verification, validation, and hazard analysis must be performed. Software documentation must include a description of the algorithms used to generate device output.
- (3) Performance testing must demonstrate the electrical safety and electromagnetic compatibility (EMC) of the device.
- (4) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (5) A light hazard assessment must be performed for all eye-tracking and visual display light sources.
- (6) Labeling must include:
  - (i) A summary of clinical performance testing conducted with the device, including sensitivity, specificity, positive predictive value, negative predictive value, and test-retest reliability;
  - (ii) A description of any normative database that includes the following:
    - (A) The clinical definition used to establish a “normal” population and the specific selection criteria;
    - (B) The format for reporting normal values;
    - (C) Examples of screen displays and reports generated to provide the user results and normative data;
    - (D) Statistical methods and model assumptions; and
    - (E) Any adjustments for age and gender.
  - (iii) A warning that the device should only be used by trained healthcare professionals;
  - (iv) A warning that the device does not identify the presence or absence of traumatic brain injury or other clinical diagnoses;
  - (v) A warning that the device is not a standalone diagnostic; and
  - (vi) Any instructions to convey to patients regarding the administration of the test and collection of test data.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact [CDRHProductJurisdiction@fda.hhs.gov](mailto:CDRHProductJurisdiction@fda.hhs.gov).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the traumatic brain injury eye movement assessment aid they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Patrick Antkowiak at 240-402-3705.

Sincerely,

Angela C. Krueger  
Deputy Director, Engineering and Science Review  
Office of Device Evaluation  
Center for Devices and Radiological Health