September 26, 2022

Neuro-Eye Diagnostic Systems LLC
% Isabella Schmitt
Director of Regulatory Affairs
Proxima Clinical Research, Inc.
2450 Holcombe Blvd.
Houston, Texas 77071

Re: K203594
Trade/Device Name: EyeCTester
Regulation Number: 21 CFR 886.1330
Regulation Name: Amsler Grid
Regulatory Class: Class I
Product Code: QTW

Dear Isabella Schmitt:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 7, 2022. Specifically, FDA is updating this SE Letter as an administrative correction for a typographical error in your Trade/Device Name.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 240-402-4662, Elvin.Ng@fda.hhs.gov.

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

September 7, 2022

Neuro-Eye Diagnostic Systems LLC
% Isabella Schmitt
Director of Regulatory Affairs
Proxima Clinical Research, Inc.
2450 Holcombe Blvd.
Houston, Texas 77071

Re: K203594
Trade/Device Name: EyeQTester
Regulation Number: 21 CFR 886.1330
Regulation Name: Amsler grid
Regulatory Class: Class I
Product Code: QTW
Dated: June 4, 2021
Received: June 14, 2021

Dear Isabella Schmitt:

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,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Respiratory, ENT and Dental Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203594

Device Name
EyeCTester Monitoring App

Indications for Use *(Describe)*
The EyeCTester Model iOS is a mobile software as a medical device (SaMD) app for adults ages 22 and above. It is intended to serve as an aid to eyecare providers to monitor and detect central / paracentral visual distortions (maculopathies) as well as central 10-degree visual field scotomas.

EyeCTester is not intended to screen or diagnose, but it is intended to alert a healthcare provider of any changes in a patient's central visual status. The device is intended for both at-home and clinical use. The EyeCTester is indicated to be used only with compatible mobile devices.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Owner:	Neuro-Eye Diagnostic Systems, LLC 2020 Quenby Street Houston, TX 77005
Official Contact:	Jade Schiffman, MD Telephone: +1 (281) 701-0577 E-mail: jschiffman@neuroeye.com
Representative Consultant Contact:	Isabella Schmitt, RAC Proxima Clinical Research, Inc. 2450 Holcombe Blvd, Suite J Houston, TX 77021 Telephone: +1 (404) 205-4653 E-mail: Isabella@ProximaCRO.com
Date Summary Prepared:	06 September 2022
Trade Name:	EyeCTester – Monitoring application
Common Name:	Digital Amsler Grid
Classification:	Class I
Classification Number(s):	21 CFR 886.1330
Product Code(s):	QTW
Classification Advisory Committee:	Ophthalmology
Predicate Device(s):	Alleye (K180895)

Device Description:

The EyeCTester - Monitoring Application comprises a survey and a series of tests to provide remote monitoring of the patient's visual parameters from the patient's home. The EyeCTester – Monitoring application is available to patients with a prescription from the healthcare provider managing their vision. Prescribed, routine patient testing via the app allows providers to monitor vision health in the interim period between visits to the physician's clinical practice. The tool is not intended to replace the need for an in-person eye exam with a professional eye care provider. EyeCTester is not intended to diagnose the patient; diagnosis and management is the responsibility of the qualified team prescribing and interpreting the app measurements.

Prior to regular, at-home use, patients will receive training in the clinic and will then undergo training within the app and verify their understanding of how to complete testing. Pop-ups will appear throughout the app reminding the patient that the app's purpose is to monitor changes in vision, not to provide a diagnosis.

The app uses an Amsler Grid test to detect changes in visual distortions / scotomas / field cuts within the central 10 degrees of vision. The test prompts patients to outline and define distorted and/or missing areas on a series of grids while staring at a pulsating fixation point. At the end of the test, the grids are combined to display the patient's responses. The results of the assessments are summarized in a report that is provided to the prescribing healthcare provider to be interpreted and evaluated for any changes over time. A comparison of the EyeCTester application with its predicate is shown in the table below.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, for functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review.

Table 1: Comparison of EyeCTester - Monitoring Application to Identified Predicate

Specification	EyeCTester (Subject Device)	Alleye
510(k) Number	K203594	K180895
Product Name	EyeCTester App	Alleye
Sponsor	Neuro-Eye Diagnostic Systems, LLC	Oculocare Medical AG
Product Code(s)	QTW	HOQ
Regulation Number(s)	21 CFR 886.1330	21 CFR 886.1330
Classification	Class I	Class I
Rx / OTC	Rx Only	Rx Only
Indications for Use	The EyeCTester Model iOS is a mobile software as a medical device (SaMD) app for adults ages 22 and above. It is intended to serve as an aid to eyecare providers to monitor and detect central / paracentral visual distortions (maculopathies) as well as central 10-degree visual field scotomas.	The Alleye is a mobile medical software application indicated for the detection and characterization of metamorphopsia, a visual distortion, in patients with age-related macular degeneration (AMD) and as an aid in the monitoring of the progression of this condition in respect of

Specification	EyeCTester (Subject Device)	Alleye
	EyeCTester is not intended to screen or diagnose, but it is intended to alert a healthcare provider of any changes in a patient's central visual status. The device is intended for both at-home and clinical use. The EyeCTester is indicated to be used only with compatible mobile devices.	metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home.
Testing Setting	At home and in clinic	At home
Hardware Platform	Software application to be used at home on a patient's personal smartphone or in clinic on an office supplied smartphone	Software application to be used at home on a patient's personal smartphone
Amsler Grid / Visual Field Algorithm	Measures 10-degree visual field for distortions, including crooked and doubling, and missingness defects, via presentation of a series of grids on which a user fixes their vision and manually selects and identifies areas of visual defects.	Measures visual field for distortions, including crooked defects, through an alignment hyperacuity task
Data Upload and Storage	Vision test data are uploaded from the patient's smartphone to a HIPAA and HiTech-compliant server. The data are presented on an online physician dashboard and within the provider's app for review and comparison by the prescribing healthcare professional.	Vision test data are uploaded from the patient's phone and are stored and transmitted in encrypted form. The Alleye platform is HIPAA-compliant, and Alleye data is stored on physical servers. The data are presented on an online physician dashboard for review and comparison by the prescribing healthcare professional.

Intended Use / Indications for Use:

The EyeCTester Model iOS is a mobile software as a medical device (SaMD) app for adults ages 22 and above. It is intended to serve as an aid to eyecare providers to monitor and detect central / paracentral visual distortions (maculopathies) as well as central 10-degree visual field scotomas.

EyeCTester is not intended to screen or diagnose, but it is intended to alert a healthcare provider of any changes in a patient's central visual status. The device is intended for both at-home and clinical use. The EyeCTester is indicated to be used only with compatible mobile devices.

Technological Characteristics:

The EyeCTester application provides remote visual monitoring for patients through Amsler Grid testing. Patients complete prescribed testing protocols within the application for one or both eyes

as assigned by their eyecare provider. Providers are then able to access and interpret the results of these tests through the app or an online server and share them with the patient after interpretation, as appropriate. Providers may also be alerted when changes in visual parameters are reported by patients through the testing, based on prespecified rules set by the provider or clinic.

Software Testing:

The software development and testing was executed in compliance with IEC 62304 *Medical Device Software Life Cycle Processes*. The results of these tests indicate that EyeCTester Amsler Grid/ Visual Field functionality is substantially equivalent to the predicate device.

Human Factors / Usability Engineering Testing:

NEDS conducted a Human Factors Validation study in which participants without visual defects were enrolled to assess the user performance and test results of the EyeCTester compared to the standard, in-office examination tools. Each participant underwent the tests twice to ensure the validity of the findings. The Human Factors Validation study indicated minimal human error risks, many of which are shared with the non-digital test analogs. Additionally, the digital, at-home, mobile (smartphone) format allow considerable improvements to the test environment and test preparation (e.g., education in a quiet and self-paced environment), compared to non-digital test analogs. Overall, all participants were observed to safely use EyeCTester's features. Based on the results from this study, the risk profile of the application is confirmed to be acceptable. The Human Factors Validation study has shown that the EyeCTester application is safe and effective for the intended users, uses, and use environments.

Clinical Testing:

Clinical testing was performed to validate the visual parameter assessments of the EyeCTester compared to the standard of care modality (paper Amsler Grid) in both healthy volunteers and patients with neuro-ophthalmic, retinal, and other diseases. Both studies were approved by wcgIRB.

These clinical studies were prospective, randomized, cross-over, 2-site studies that involved a test and re-test to evaluate repeatability and agreement between the subject device and the paper format. These studies demonstrated that a patient may use the EyeCTester application to gather psychophysiological measurements of central and paracentral vision parameters related to normative functioning of the human visual system, and these measurements are useful for remote monitoring in between clinic visits.

The data from this clinical study provide affirmation that the EyeCTester app-based test is repeatable and consistent with the results of the paper analogue. The Amsler Grid testing was consistent and repeatable across the two testing methods. An additional metric assessed during the study was rate of human error in completing the test. It was confirmed that the human error rate was below 1% in the EyeCTester app test. Overall, the clinical evaluations support the use of the EyeCTester for testing patients using the Amsler Grid test.

Conclusion:

In conclusion, the NEDS EyeCTester – Monitoring Application is demonstrated to be as safe and effective and perform as well as the identified predicate device. The Amsler Grid test has the same intended use, indication, technological characteristics, and principles of operation as the predicate. Any differences between the EyeCTester application's functionalities and the predicate device's do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when use as labelled. Clinical and Human Factors testing demonstrate that the device performs as intended. Thus, the EyeCTester application is substantially equivalent to the identified predicate devices.