June 27, 2018

Oculocare Medical AG
% Allison Komiyama
Consultant
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn St.
San Diego, CA 92104

Re: K180895
Trade/Device Name: Alleye
Regulation Number: 21 CFR 886.1330
Regulation Name: Amsler Grid
Regulatory Class: Class I
Product Code: HOQ
Dated: March 30, 2018
Received: April 5, 2018

Dear Allison Komiyama:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley S. Cunningham -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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)*
K180895

Device Name
Alleye

Indications for Use *(Describe)*
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 metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary
# K180895

**DATE PREPARED**
June 20, 2018

**MANUFACTURER AND 510(k) OWNER**
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**PROPRIETARY NAME OF SUBJECT DEVICE**
Alleye

**COMMON NAME**
Grid, Amsler

**DEVICE CLASSIFICATION**
21 CFR 886.1330 Amsler Grid
Product Code HOQ, Class I

**PREMARKET REVIEW**
ODE/DOED/DSDB
Ophthalmic

**INDICATIONS FOR USE**
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 metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home.

**DEVICE DESCRIPTION**

Alleye is a digital technology visual function test, consisting of two different items: a mobile app for patients and a web interface for eye care professionals. Alleye implements an alignment hyperacuity task that helps patients with age-related macular degeneration (AMD) to assess their vision at home. This allows the timely detection of significant changes in vision function, enabling the regular monitoring of the disease progression and/or monitoring the visual function associated with ongoing treatments. Two elements provide feedback about the Alleye test: a score and a colored circle. The score value reflects the visual performance in the dots alignment, whereas the color indicates whether the performance has worsened considerably (red) or remained stable or improved (green) compared to the previous test.

**PREDICATE DEVICE IDENTIFICATION**

Alleye is substantially equivalent to the following predicate:

| *510(k) Number* | *Predicate Device Name / Manufacturer* | *Primary Predicate* |
|---|---|---|
| K143211 | myVisionTrack Model 0005 / Vital Art and Science, LLC | ✓ |

**SUMMARY OF NON-CLINICAL TESTING**

No FDA performance standards have been established for Alleye. The following tests were performed to demonstrate safety based on current industry standards:

- Software Verification: The software development and testing was executed in compliance to IEC 62304 *Medical Device Software - Software Life Cycle Processes*

The results of these tests indicate that Alleye is substantially equivalent to the predicate device.

**SUMMARY OF CLINICAL TESTING**

The clinical performance of Alleye was evaluated in accordance with ISO 14155 *Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice.*

- Test-Retest Study: the reliability of the metamorphopsia testing with Alleye was evaluated in a test-retest study performed on 26 healthy subjects and 60 subjects with age-related macular degeneration (AMD).
- Clinical Evaluation – Longitudinal Study: This study evaluated the extent to which regular patient self-measurement with Alleye performed between two clinical visits provides an aid in the monitoring for the need of an injection at the next follow-up visit. The 60 patients evaluated in this study had been diagnosed with wet AMD and were undergoing a *pro re nata* intravitreal injection (IVI) of anti-VEGF for treatment. They had completed at least a follow-up of 3 months, providing 1506 Alleye measurements in 150 follow-up periods. This clinical study demonstrates that patient self-testing with Alleye allows the detection of worsening visual function prior to follow-up visits.
- Usability Study: The usability of the Alleye app was evaluated on elderly subjects with AMD, in two clinical studies. The subjects provided oral feedback on the mobile app's user-friendliness and filled out the System Usability Scale.

The results of these studies demonstrate that Alleye is substantially equivalent to the predicate device.

**EQUIVALENCE TO PREDICATE DEVICES**

Oculocare believes that Alleye is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar intended use, and similar technological characteristics (mobile app for hyperacuity self-testing) as the device cleared in K143211. The principle of the hyperacuity testing is similar to the predicate as it involves global visual integration, and no fixation is required to perform the test. The main difference between the subject device and the predicate device is the task being used to assess the patient. The subject device incorporates the use of an alignment hyperacuity task whereas the predicate device is based on a shape discrimination hyperacuity task. The subject device has undergone clinical testing to ensure the device is as safe and effective as the predicate.

**CONCLUSION**

Based on the software validation and clinical evaluation, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use and technological characteristics for Alleye are assessed to be substantially equivalent to the predicate device. The device is considered safe and effective for its intended use.