



September 28, 2018

RightEye, LLC  
Adam Gross  
Chief Executive Officer  
7979 Old Georgetown Rd., Suite 801  
Bethesda, Maryland 20814

Re: K181771  
Trade/Device Name: RightEye Vision System  
Regulation Number: 21 CFR 882.1460  
Regulation Name: Nystagmograph  
Regulatory Class: Class II  
Product Code: GWN  
Dated: June 29, 2018  
Received: July 3, 2018

Dear Adam Gross:

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/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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

**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

## Indications for Use

510(k) Number (if known)  
K181771

Device Name  
RightEye Vision System

Indications for Use (Describe)

The RightEye Vision System is intended for recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## **5.0 510(K) SUMMARY**

**Prepared Date:** September 27, 2018

### **Submitter Information:**

*Company:* RightEye, LLC  
7979 Old Georgetown Rd., Suite 801  
Bethesda, MD 20814

*Contact Person:* Adam Gross  
CEO  
Tel: (301) 979-7970

### **Device Information:**

*Trade Name:* RightEye Vision System

*Common Name:* Nystagmograph

*Classification Name:* 21 CFR 882.1460

*Device Class:* Class II

*Product Code:* GWN

**Predicate Device:** **EYE-SYNC (K152915)**  
SyncThink, Inc.

### **Device Description:**

RightEye Vision System detects involuntary eye movement behavior for the purpose of visual tracking. The RightEye Vision System is designed to provide accurate and reliable information for users to supplement and inform clinical decision-making. RightEye Vision System provides objective metrics acquired from eye movements measured and recorded by a hardware eye tracker that are not observable in clinical observation. Results of each RightEye Vision System assessment are transferred and stored remotely on a web server. All personal health information data are encrypted with HTTPS (HTTP Secure) protocol. The remote web server software calculates metrics from the assessment data and provides quantitative outputs and supporting graphics. The software can track the results over time showing changes in metrics, trendlines, graphs, visuals, and gaze replay. The user accesses these results by logging into the RightEye web portal.

The RightEye Vision System is designed to run on Windows 10 operating systems and the web portal has been optimized for Chrome. RightEye Vision System is programmed to run on a specific hardware setup, the Tobii Dynavox i15. It is deployed as a pre-loaded system on hardware provided and managed by RightEye.

### **Indications for Use:**

The RightEye Vision System is intended for recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.

**Comparison to Predicate Device:**

The predicate device is the EYE-SYNC (K152915), which is manufactured by SyncThink, Inc. and is intended for recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.

The RightEye Vision System is substantially equivalent to EYE-SYNC (manufactured by SyncThink, Inc.; K152915). The RightEye Vision System and the EYE-SYNC share the same intended use as a Nystagmograph. The products are also similar in terms of technological characteristics as both electronically record objective measurements of eye movement. Neither device provides a diagnosis or any diagnostic recommendations. Both devices are used by physicians or clinicians. Differences in the design and performance of the RightEye Vision System from EYE-SYNC do not affect either the safety or effectiveness of the RightEye Vision System for its intended use.

	<b>SUBJECT DEVICE: RightEye Vision System RightEye, LLC</b>	<b>PREDICATE DEVICE: EYE-SYNC (K152915) SyncThink, Inc.</b>
<b>Classification Name</b>	Nystagmograph	Nystagmograph
<b>Device Class</b>	Class II	Class II
<b>Product Code</b>	GWN (21 CFR 882.1460)	GWN (21 CFR 882.1460)
<b>Intended Use</b>	Nystagmograph	Nystagmograph
<b>Indication for Use</b>	Recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.	Recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.
<b>Device Technology</b>	Eye-tracking system with pre-loaded software on manufacturer-provided hardware.	Eye-tracking system with pre-loaded software on manufacturer-provided hardware.
<b>Eye tracking method</b>	Includes a remote camera and light source for recording eye movement. Stimuli are presented to the user via a monitor as the projection surface to elicit involuntary eye movements. The function and intent are identical.	Includes a remote camera and light source for recording eye movement. Stimuli are presented to the user via a monitor as the projection surface to elicit involuntary eye movements. The function and intent are identical.
<b>Software</b>	Has software which records the eye tracking methods for patient's eye movements (fixation, pursuit and saccade) while he/she follows the stimulus. This software function is performed to support the recording, viewing and analyzing of horizontal and vertical eye movements. The software uses proprietary algorithms to perform the analysis for the reporting of involuntary and voluntary eye movements but the function and intent are identical.	Has software which records the eye tracking methods for patient's eye movements (fixation, pursuit and saccade) while he/she follows the stimulus. This software function is performed to support the recording, viewing and analyzing of horizontal and vertical eye movements. The software uses proprietary algorithms to perform the analysis for the reporting of involuntary and voluntary eye movements but the function and intent are identical.
<b>Hardware</b>	Uses an all-in-one device that contains a computer to record the eye movements.	Uses a tablet to record the eye movements.
<b>User Data &amp; Reports</b>	Uploads user data and reports to a secure web portal.	Uploads user data and reports to a secure web portal.

**Supporting Information:**

Software testing was conducted in accordance with FDA's May 2005 guidance document entitled, "Guidance for Industry and FDA Staff. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to a minor injury. Software validation and verification demonstrate that the RightEye Vision System performs as intended and meets its specifications.

Validation testing, including test-retest reliability and accuracy, has confirmed the performance of the RightEye Vision System for its intended use.

**Conclusion:**

The RightEye Vision System falls within the type of device regulated under 21 CFR 882.1460 and Product Code GWN and has the same intended use as its predicate device. Differences in the design and performance of the RightEye Vision System from the predicate device do not affect either the safety or effectiveness of the RightEye Vision System for its intended use. Therefore, the RightEye Vision System is substantially equivalent to the predicate device.