DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 29, 2016

SyncThink, Inc.
% Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K152915
Trade/Device Name: EYE-SYNC™
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: December 23, 2015
Received: December 28, 2015

Dear Ms. O'Connell:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
EYE-SYNC

Indications for Use *(Describe)*
The EYE-SYNC 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.

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510(k) SUMMARY

SyncThink, Inc.
EYE-SYNC

510(k) Owner
SyncThink, Inc.
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Submission Correspondent
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Date Prepared: January 25, 2016

Trade Name of Device
EYE-SYNC

Common or Usual Name
Nystagmograph

Classification Name
21 C.F.R. 882.1460
Nystagmograph
Product Code GWN

Predicate Device
Fall Prevention Technologies, LLC balanceback Mobile Intuitive VNG System (K070729)

Intended Use / Indications for Use
The EYE-SYNC is intended for recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.

Device Description

SyncThink's EYE-SYNC™ consists of two components. These components are provided as a system with preloaded software. The EYE-SYNC is a fully-integrated, head-mounted eye-tracking system with two primary system components: 1) the head mounted display, containing the eye-tracking hardware and software system; and, 2) an integrated handheld peripheral used to administer the test and store testing results. The eye tracking unit includes two high-speed infrared cameras connected to a dedicated image analysis computing system. Camera lighting is provided by 12 high quality Light-emitting Diodes (LEDs) centered at 850 nanometers.

EYE-SYNC is a less than one minute, non-invasive eye-tracking test that provides a quantitative representation of attention using precise measurements of eye gaze position relative to a target stimulus. Eye gaze tracking is performed using a proprietary implementation of the pupil-corneal reaction method. Display and eye tracking are controlled using the attached Windows-based handheld. Batteries provide power for remote use (away from power source).

As a subject tracks a predictable moving target that follows a circular trajectory on a screen within the head mounted system, eye gaze position and time stamp are recorded by the use of cameras in the head mounted system. Multiple eye gaze positions relative to the target stimulus are measured and analyzed for position error variability using installed software, and the results are displayed and stored on the handheld peripheral

Performance Data

No performance data was required or provided. Software validation and verification demonstrate that the EYE-SYNC performs as intended and meets its' specifications.

Substantial Equivalence

EYE-SYNC is substantially equivalent to Fall Prevention Technologies, LLC's balanceback Mobile Intuitive VNG System cleared in K070729**.** As explained in more detail below, EYE-SYNC has the same intended use, and similar principles of operation and similar technological characteristics as the previously cleared predicate device**.** Thus, EYE-SYNC is substantially equivalent to its predicate.

The intended use of the EYE-SYNC and the intended use of the balanceback Mobile Inuitive VNG System are the same. Both devices are intended for recording, viewing, and analyzing eye movements in support of identifying specific types of impairment. The EYE-SYNC device performs these activities

to identify visual tracking impairment while the balanceback device attempts to identify balance disorders. Neither device provides a diagnosis or any diagnostic recommendations. Both devices are used by physicians or clinicians.

Both devices have the same technological characteristics. Both devices consist of a computing device with software and goggles. The EYE-SYNC utilizes a tablet while the balanceback system uses a computer. This difference in the form of the computing device has no impact on the functionality performed by the computing device.

Both devices include goggles with a camera and a light source. In both cases stimuli are displayed to the patient for the purpose of conducting eye movement tests. Both devices contain a head-mounted display system. The balanceback system projects the visual stimulus onto a front-facing surface, while the EYE-SYNC is the projection surface. The intent and functionality are identical.

The tests conducted with EYE-SYNC are a subset of the tests conducted by the balanceback system. This difference in the exact tests offered does not impact the safety or effectiveness as the tests offered by the EYE-SYNC are a subset of the tests offered on the balanceback system and are the tests necessary to allow evaluation of visual tracking impairment.

Both systems have software which records the patient's eye movements while he/she follows the stimulus. For both devices, this is performed to support the recording, viewing and analyzing of horizontal and vertical eye movements.

Therefore, the EYE-SYNC is substantially equivalent to the balanceback Mobile Intuitive VNG System.