



October 2, 2021

SyncThink, Inc.
% Allison Kumar
Regulatory Consultant
Arina Consulting, LLC
27 Hilltop Dr
San Carlos, California 94070

Re: K202927

Trade/Device Name: EYE-SYNC
Regulation Number: 21 CFR 882.1455
Regulation Name: Traumatic brain injury eye movement assessment aid
Regulatory Class: Class II
Product Code: QEA
Dated: August 18, 2020
Received: September 29, 2020

Dear Allison Kumar:

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,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K202927

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.

The EYE-SYNC® is intended to record, measure, and analyze eye movements as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), within three days of sport-related head injury in patients 17-24 years of age in conjunction with a standard neurological assessment, for use by medical professionals qualified to interpret the results of a concussion assessment examination.

A negative EYE-SYNC® classification corresponds to eye movements that are consistent with a lack of concussion.

A positive EYE-SYNC® classification corresponds to eye movements that may be present in patients with concussion.

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.

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510(k) Summary

This summary is being submitted in accordance with the requirements of 21 CFR Part 807.92.

510(k) Owner Information:

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Submission Correspondent:

Allison Kumar
Arina Consulting, LLC
allison@arinaconsulting.com

Device Information:

Trade Name: EYE-SYNC
Device: Traumatic Brain Injury Eye Movement Assessment Aid
Regulation: 882.1455
Classification Panel: Neurology
Device Class: 2
Product Code: QEA

Predicate Device:

Ocologica EyeBOX (DEN170091)

Reference Devices:

SyncThink EYE-SYNC (K152915), GN Otometric 1068 A/S Type 1085 ICS
Impulse (K151504)

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.

The EYE-SYNC® is intended to record, measure, and analyze eye movements as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI), within three days of sport-related head injury in

patients 17 -24 years of age in conjunction with a standard neurological assessment, for use by medical professionals qualified to interpret the results of a concussion assessment examination.

A negative EYE-SYNC® classification corresponds to eye movements that are consistent with a lack of concussion.

A positive EYE-SYNC® classification corresponds to eye movements that may be present in patients with concussion.

Device Description:

The SyncThink EYE-SYNC device is a portable, fully enclosed eye tracking environment with three primary components:

1. Eye Tracker (head-mounted device) with eye tracking sensor
2. Eye tracking display
3. Android Tablet

The eye tracker is a modified Samsung GearVR provided by SensoMotoric Instruments (SMI). It is mounted to the subject's face and held either by hands placed on the side or using a strap. The eye tracking sensor includes two high-speed infrared cameras (for each eye) connected to a visual display for battery, computation, and display. Camera lighting is provided by 12 high-quality Light-emitting Diodes (LEDs) centered at 850 nanometers. Eye gaze tracking is performed using a proprietary implementation of the pupil- corneal reaction method. The eye tracker display is a non-networked mobile device that fits within the eye tracking sensor and connects over USB. The display receives eye tracking sensor information for post-processing, manages sensor calibration, provides binocular visual display to the subject, and interfaces with the Android tablet over Bluetooth. Eye gaze tracking and visual display is combined to provide several assessment paradigms to characterize subject eye tracking performance:

- Smooth Pursuit
- Saccades
- Vestibular-Ocular Reflex (VOR)
- VOR Cancellation (VORx)

An EYE-SYNC software app on the display device manages these functions.

The Android tablet is a standard off-the-shelf 9.7" mobile tablet from Samsung with Verizon 4G cellular connectivity. A second EYE-SYNC software app designed to provides an integrative platform for data collected on the HMD eye tracker:

- Patient, administrator, and records management
- Eye tracker assessment Bluetooth control
- Assessment Vestibular/Ocular-Motor Screening (VOMS) self-report tools
- Eye tracker assessment real-time Bluetooth monitoring

- Eye tracker data log Bluetooth transfer
- Eye tracker assessment analysis using visual synchronization metrics
- Analysis report generation with visualizations
- Background diagnostics to verify device health
- Cloud connectivity for data synchronization

Internal batteries from the eye tracking display and Android tablet provide power for remote use, away from power source. Each device has an EYE-SYNC software app installed to provide the described functionality. EYE-SYNC is provided as a complete system and both apps are managed a single software project with identical version numbers. EYE-SYNC is provided in a standalone carry-case with user manual, strap, cleaning, and charging accessories.

Comparison of Technological Characteristics with Predicate Device:

The claim of substantial equivalence of EYE-SYNC to the predicate device is based on a detailed comparison of several factors. This comparison is included in the table below:

	Subject Device (EYE-SYNC)	Predicate Device (Eye-BOX)	Comparison
Submission Number	K202927	DEN170091	
Product Code	QEA	QEA	SAME
Intended Use	Measure and analyze eye movement as an aid in the diagnosis of concussion	Measure and analyze eye movement as an aid in the diagnosis of concussion	SAME
Indications for Use	<p>The EYE- SYNC® is intended for recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects.</p> <p>The EYE-SYNC® is intended to record, measure, and analyze eye movements as an</p>	<p>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</p>	<p>SIMILAR Differences between the subject device and predicate include:</p> <ul style="list-style-type: none"> • Age range of population for subject device is a small subset of predicate. • Population of subject device is specific to sports-related injury. • Use of test is a shorter time period since injury compared to predicate. <p>The differences do not raise</p>

	<p>aid in the diagnosis of concussion within three days of sport-related head injury in patients 17 -24 years of age in conjunction with a standard neurological assessment, for use by medical professionals qualified to interpret the results of a concussion assessment examination and aid in the management of concussion.</p> <p>A negative EYE-SYNC® classification corresponds to eye movements that are consistent with a lack of concussion.</p> <p>A positive EYE-SYNC® classification corresponds to eye movements that may be present in patients with concussion.</p>	<p>concussion.</p> <p>A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion.</p> <p>A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion.</p>	<p>new questions of safety or effectiveness.</p>
Rx Use Only	Yes	Yes	SAME
Hardware Components	VR Headset Tablet	Stand with integrated Computer	<p>DIFFERENT</p> <p>Subject device uses VR headset to capture gaze measurements. Analysis is done via a software app on the accompanying tablet. This method has been validated with performance and clinical testing to verify it provides the same information as the</p>

			predicate device and therefore does not raise new questions of safety and effectiveness.
Wireless Communication	Bluetooth connection between VR Headset and Tablet. Tablet has 4G cellular connection Cloud.	Single, non-networked device	DIFFERENT Subject eye tracking device communicates over Bluetooth wireless to an administrative tablet for control and data exchange. The predicate device achieves the same functionality within a single computer system. Cellular connectivity to the cloud is a convenience feature and does not contribute to the IFU. Bluetooth connectivity is a common systems interface. This method has been validated with performance and clinical testing to verify it provides the same functionality as the predicate device and therefore does not raise new questions of safety and effectiveness.
Eye Tracking	Gaze	Gaze	SAME
Camera Speed	60 Hz	500 Hz	DIFFERENT Eye tracking cameras can be oversampled with respect to the signal of interest. The subject device has elected to go with a lower sample rate, but has validated this decision with performance and clinical testing to verify it provides the same functionality as the predicate device and therefore does not raise new questions of safety and effectiveness.
Stimulus Screen	60 second recording of 0.4Hz motion circulating at 10 degree radius with two sets of 6 cycles on viewing screen	220 second video circulating on discrete path of 5 cycles along perimeter of screen	DIFFERENT This method used by the subject device has been validated with performance and clinical testing to verify it provides the same information as the predicate device and

			therefore does not raise new questions of safety and effectiveness.
Software	Algorithm provides analysis and results	Algorithm provides analysis and results	SAME
Patient Contacting Materials	Yes – Foam cushion on face mask.	N/A	Different Patient contacting material is biocompatible. Does not raise new questions of safety or effectiveness.
Sterility	Non-Sterile	Non-Sterile	SAME
EMC and Electrical Safety	IEC 60601-1:2012 IEC 60601-1-2:2014	IEC 60601-1:2012 IEC 60601-1-2:2014	SAME
Performance Testing - Bench	Light Safety	Light Safety	SAME
Performance Testing - Clinical	82% sensitivity (74%, 89%) 93% specificity (91%, 94%) 56% PPV*** (48%, 64%) 98% NPV*** (97%, 99%)	80.4% sensitivity (66.1%, 91.9%) 66.1% specificity (59.7%, 72.1%) 31.6%% PPV (23.3%, 40.9%) 94.5% NPV (89.9%, 97.5%)	Similar Results from clinical testing* are substantially equivalent to predicate device**
Special Controls	Yes	Yes	SAME

*Clinical performance analysis did not include assessments with poor eye-tracking quality. In these cases, the device does not provide an assessment result.

**95% Confidence intervals noted for the subject and predicate device are derived from Clopper-Pearson method. 95% Confidence intervals for the subject device derived using the Wilson Score method for sensitivity are (74%, 88%) and (91%, 94%) for specificity.

*** PPV and NPV was obtained from observed study data without adjustment of the prevalence (10%).

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the EYE-SYNC device. The system complied with the IEC 60601-1:2012 Ed. 3.0 standard for operator and patient safety and IEC 60601-1-2:2014 Ed 4.0 standard for EMC in the intended use environment. The system complied with IEC 60601-2-57:2011 Ed1.0 Medical electrical equipment – Part 2 for safety of non-laser light source equipment intended for diagnostic use.

Software Verification and Validation Testing and Cybersecurity

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's 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 a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator, either directly or indirectly through incorrect or delayed information or through the action of a care provider.

Cybersecurity was assessed and documented according to the FDA Guidance, "Off-the-shelf Software – Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software."

Performance Testing – Bench

Testing was performed to demonstrate conformance with the following standards:

- EN62471 *Photobiological Safety of Lamps and Lamp Systems*

Biocompatibility Testing

The biocompatibility evaluation of the EYE-SYNC device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,' May 1, 1005, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Sterility

The device is provided non-sterile. Cleaning instructions are provided in

the user manual.

Summary of Clinical Testing:

Clinical performance

Clinical data was submitted to support substantial equivalence and conform to special controls. Validation data analysis was performed on 1,069 subjects. The validation study population included subjects ages 17-24 years actively engaged in competitive athletics. Of these 1,069 subjects, 107 subjects met the SCAT-5 clinical reference standard definition of concussion, where the evaluations were conducted by a healthcare practitioner blinded to EYE-SYNC device output +3 days from injury.

Retrospective analysis determined 82% (74%, 89%) sensitivity and 93% (91%, 94%) specificity of the EYE-SYNC test. Negative predictive value made by the classifying algorithm was 98% (97%, 99%) and positive predicative value was 56% (48%, 64%). For PPV and NPV reference, the study prevalence of clinical classification of concussion (mTBI) was 10% (107/1069). The analysis validates the clinical utility of the eye-tracking assessment as an aid in diagnosis of concussion within three days of sport-related head injury.

Test-retest reliability

The test-retest reliability of the EYE-SYNC metrics were reported through an independent study of 150 athletes from 11 sports with a mean (SD) age of 20 (1.3) years and 55% female population. The Intra-class correlation (ICC) was calculated with its 95%CI for each EYE-SYNC metric:

- SD tangential error: 0.86 (0.82, 0.90)
- SD radial error: 0.78 (0.71, 0.84)
- Mean phase error: 0.83 (0.77, 0.87)

The ICC describes the level of correlation between two or more observations made on the same student athlete; a higher ICC (closer to 1) indicates greater reliability of the measure.

Conclusion:

The non-clinical and clinical data support the safety of the device and the software verification and validation demonstrate that SyncThink's EYE-SYNC device should perform as intended in the specified use conditions, and which are comparable to the predicate device that is currently marketed for the same intended use.