SyncThink, Inc. 7/31/17

U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

JULY 31, 2017
WARNING LETTER

Mr. Ernest Santin
CEO
SyncThink, Inc.
54 Canal Street
Suite 200
Boston, Massachusetts, 02114

Re: EYE-SYNC
Refer to CMS #498523

Dear Mr. Santin:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing the EYE-SYNC device in the United States, without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). Under Section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body.

The FDA has reviewed your firm's website at www.syncthink.com and determined that the EYE-SYNC device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g), for the device as described and marketed. The EYE-SYNC device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution this device with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii).

Specifically, the EYE-SYNC device was cleared as a prescription device under K152915 with the following indications for use: recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects. However, your firm's promotion of the device provides evidence that the device is intended for cognitive assessment/testing of concussions and head trauma, including in injured athletes and soldiers**,** which would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval. Examples from your company's website include, but are not limited to:

- "In the clinic or at the point of injury: advanced cognitive assessment."
- "Introducing the future of mobile assessment technology: EYE-SYNC® by SyncThink overcomes the limitations of traditional cognitive testing to provide an easy-to-use, rapid, objective tool for initial screening and recovery monitoring."
- "Mobile, precise assessment of visual attention after a force to the head: EYE-SYNC® uses high-performance, cutting-edge eye tracking technology to monitor eye movement in a handheld virtual reality environment. If your brain is out of sync after an on-field incident, SyncThink®'s technology will let you know in less than a minute."
- "Screening and Recovery: EYE-SYNC® helps you with screening in the field and assessing return to play or work in the clinic."
- "EYE-SYNC® is fast. Every second counts when assessing cognitive state on the field. EYE-SYNC®'s core technology takes less time than a medical timeout to administer."
- "EYE-SYNC® is reliable. SyncThink® has tested its metrics on over 10,000 soldiers and athletes and shown a greater than 0.8 test-retest reliability-far exceeding other cognitive tests."
- "In the clinic or at the point of injury: Cognitive assessment tools are tedious, inaccurate, or immobile. EYE-SYNC® delivers world-class clinical tools from the

playing field to the battlefield. Follow-up with the same toolset in a clinical setting to determine return-to-activity evaluation."

- "Coaches and trainers need to make fast on-field decisions that might place an athlete in harm's way. The EYE-SYNC® is a mobile, objective assessment that provides clarity after an injury."
- "EYE-SYNC® is a functional assessment that provides real-time information to commanders on the battlefield. Spot and care for injury before it becomes a danger to the mission."
- "Stanford Sports Medicine uses EYE-SYNC® technology currently to screen athletes for concussion and make decisions on return to play."

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/defaul FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that SyncThink, Inc. immediately cease activities that result in the misbranding or adulteration of the EYE-SYNC device, such as the commercial distribution of the device for the uses discussed above.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Food and Drug Administration

Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Rm 3540
10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number CMS # 498523 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Shanika Booth, Chief, Surveillance and Enforcement Branch II at (301) 796-5770 or fax (301) 847-8138.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely,
/S/
CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and
Radiological Health

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