FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

November 6, 2022

Katherine Price Snedaker, LCSW
CEO and Founder
PINK Concussions
15 Shorefront Park
Norwalk, CT 06854

Re: Citizen Petition – Docket Number FDA-2022-P-0234

Dear Ms. Snedaker:

This letter responds to your citizen petition dated February 26, 2022 (CP), which was received and filed by the Food and Drug Administration (FDA) on February 27, 2022. Your petition requests FDA to "rescind SyncThink, Inc.'s 510(k) clearance K202927 for EYE-SYNC Indications for Use (IFU) as an aid in diagnosis of concussion."

FDA has reviewed the petition in accordance with 21 CFR 10.30(e) and denies your request for the reasons discussed below.

I. Background

On September 29, 2020, SyncThink, Inc. submitted a 510(k) notification for EYE-SYNC as a traumatic brain injury eye movement assessment aid. On October 2, 2021, FDA cleared EYE-SYNC as a traumatic brain injury eye movement assessment aid. FDA found the EYE-SYNC substantially equivalent to the Oculogica EyeBOX.

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.[1]

Your petition requests that FDA reconsider and rescind its 510(k) clearance of EYE-SYNC because: (1) the EYE-SYNC device does not provide any "addition to sensitivity or specificity for assessment of concussion to the self-reported concussion symptom checklist that is required it be used in conjunction with"; (2) the clinical trial subject population only included subjects

[1] See 510(k) summary available at https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202927.pdf.

with concussions; and (3) the clinical trial design is unacceptable. Further, you allege that because of the allegations listed above, clearance of the EYE-SYNC device is not in the public interest.

II. Discussion

FDA cannot rescind a 510(k) for the reasons you provided. The United States Court of Appeals for the District of Columbia Circuit ruled that FDA could not rely on inherent reconsideration authority to rescind its initial substantial equivalence determination. *Ivy Sports Medicine, LLC v. Burwell*, 767 F.3d 81 (D.C. Cir. 2014), reh'g en banc denied, 2015 U.S. App. LEXIS 4140 (D.C. Cir. Mar. 13, 2015) (*Ivy Sports*)[2]. Because FDA lacks inherent reconsideration authority for the reasons you provided, FDA denies your request to reconsider and rescind 510(k) clearance K202927.

If you have any questions regarding this response, please contact Brandy Edmonds, J.D., at Brandy.Edmonds@fda.hhs.gov or 301-796-8676.

Sincerely yours,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S
Date: 2022.11.06 16:42:51 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health

[2] The court in *Ivy Sports* stated that it was "unnecessary to decide" whether FDA may rescind a 510(k) clearance "obtained through fraud, ex parte contacts, or other misconduct tainting the original record and thereby affecting the integrity of an agency's proceedings.'' See *Ivy Sports Medicine*, 767 F.3d at 88 (quoting *American Methyl Corp. v. EPA*, 749 F.2d 826, 834 n.51 (D.C. Cir. 1984)). You have not alleged that such issues or similar circumstances exist here.