July 28, 2022

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

Sent via email to: Katherine@PINKconcussions.org

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

Dear Ms. Snedaker:

This is an interim response to the petition dated February 26, 2022, filed by the Food and Drug Administration (FDA) on February 27, 2022. In the petition, you requested FDA rescind SyncThink, Inc.'s 510(k) clearance K202927 for EYE-SYNC Indications for Use (IFU) as an aid in the diagnosis of a concussion.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Brandy Edmonds in our Office of Policy at (301) 796-8676.

Sincerely yours,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S
Date: 2022.07.28 15:28:57 -04'00'

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