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Dr. David P. McMullen
Director, OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
US Food and Drug Administration

September 9, 2024

RE: C230014
Product Name: Dr MOOVES A&D App
Suicide Instinct theory to address the Suicide Epidemic in the USA

Dear Dr. McMullen,

I am the official correspondent for the above-referenced request for information. I am responding to your letter dated April 4, 2024. In it, you explain that based on the information we provided, our app does not conform to the requirements of current existing regulations, and you believe the appropriate classification is through the De Novo pathway. To question this, I asked for a meeting with Abiy Desta, CDRH Ombudsman, which took place September 5, 2024. This letter documents the discussion between me and Abiy.

First, we established an understanding of the Dr. Mooves A&D app. The purpose of the Dr. Mooves A&D app is to prevent suicide in latency age children (aged 5 to 12 years). It targets treating subclinical anxiety and depression in these children. It does this by guiding the user through therapeutic dances that build the user's cognitive skills, which increase their protective factors against suicide. In other words, the app uses movement as therapy to target subclinical anxiety and depression. Additionally, we discussed each time the user does a qualifying dance, they are rewarded a micro bank deposit.

Next, we both established that the app was "safe". By safe, it means that using the app poses no more risk for the children than that encountered in daily life. Therefore, there are no safety concerns about the Dr. Mooves A&D app.

Finally, in order to obtain data to support our app, we are launching a field study using the current version of the app. The app is free to use, and we want to get feedback from users. Once we assemble the results of our field study, we will provide the results to the FDA in our response.

Please feel free to contact me if you have any questions or concerns.

Sincerely,



Victor Talbot, MD

Official Correspondent from Playing Forward & Dr.MOOVES, INC and principal creator of the Dr. MOOVES A&D app