February 18, 2021

ImagiRation LLC
Andrey Vyshedskiy
Founder and CEO, ImagiRation LLC
9 Michael Rd.
Boston, Massachusetts 02135

Re: Q210093
Trade/Device Name: Mental Imagery Therapy for Autism (MITA)
Received: January 19, 2021

Dear Andrey Vyshedskiy:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission requesting designation as a Breakthrough Device. The proposed indications for use includes "MITA is indicated to improve language in children ages 2 to 12 years diagnosed with ASD. Patients who engage with MITA demonstrate improvements in a parents-reported measures of language comprehension, Mental Synthesis Evaluation Checklist (MSEC), and expressive language, Autism Treatment Evaluation Checklist (ATEC) Language Subscale. MITA should be considered for use as part of a therapeutic program that may include: speech-language therapy and Applied Behavior Analysis (ABA) therapy." We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at https://www.fda.gov/media/108135/download.

We recommend you review the FDA guidance document for the Breakthrough Devices Program referenced above for the available mechanisms for obtaining feedback from the Agency on device development for designated breakthrough devices. When submitting any new requests, please reference Q210093. Any new submission should be provided as an eCopy, it should include the FDA reference number for this submission, and should be submitted to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You are reminded that as specified in Section 515B(g)(1) of the Federal Food, Drug, and Cosmetic Act, a Breakthrough Device Designation does not change the requirements for approval of an application for an Investigational Device Exemption under section 520(g) or marketing authorizations under section 515(c), 510(k), or 513(f)(2) of the Food, Drug, and Cosmetic Act. Additionally, the information used to support a premarket submission for a Breakthrough Device must meet the requirements of valid scientific evidence (21 CFR 860.7). You are further advised that the granting of a Breakthrough Device Designation does not guarantee that the application will ultimately be approved.

If you have any questions, please contact Ozell Sanders, PhD at 301-796-3126 or Ozell.Sanders@fda.hhs.gov.

Sincerely,

Vivek J. Pinto -S

Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health