DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 2 8 2012

Lisa Tseng, M.D.
Chief Executive Officer
hi HealthInnovations
9701 Data Park Drive
Minnetonka, Minnesota 55343

Dear Dr. Tseng:

The Food and Drug Administration (FDA) has learned that your firm is marketing the hi HealthInnovations Online Hearing Test in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). In making this determination, the Office of Compliance, in the FDA's Center for Devices and Radiological Health, reviewed the 20111202_hi_HealthInnovations.pdf slide presentation; the hi HealthInnovations Summary (dated December 18, 2011); the online hearing test, and related materials at: https://www.hihealthinnovations.com/page/hearingtest.com; and the Van Tasell article at: https://www.hihealthinnovations.com/MerchantUploads/edgeHi/Hearing%20Review%20Article%20v2.pdf.

Under section 201(h) of the Act, 21 U.S.C. § 321(h), the Online Hearing Test 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 to affect the structure or function of the body. The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country for which approval is not required.

A review of our records revealed that your firm has not obtained marketing approval or clearance before marketing the hi HealthInnovations Online Hearing Test, which is a violation of the law. Specifically, the test is adulterated under section 501(f)(1)(B) of the Act, 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). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device

into commercial distribution, as required by sections 510(k) of the Act, 21 U.S.C. § 360(k). 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 your firm needs to submit in order to obtain approval or clearance of its device is described on the internet at http://www.fda.gov/cdrh/devadevice/3122.html. The FDA will evaluate the information your firm submits and decide whether your firm's product may be legally marketed.

(b) (4) [redacted], your firm should not continue to market the device until it receives FDA clearance of the device. Continuing to market an unapproved device violates the Act, as described above, and the FDA could initiate regulatory action such as seizure, injunction, or civil money penalties against your firm. (b)(4) & (b)(5) [redacted]

Your firm should immediately cease marketing the Online Hearing Test until your firm has submitted a new 510(k) application to be reviewed for clearance by FDA. You may continue to sell hearing aid devices provided you comply with the regulations found at 21 CFR 801.420 and 801.421.

Please notify this office in writing within thirty business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including 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 (including any systemic corrective actions) 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 thirty business days, state the reason for the delay and the time within which these activities will be completed.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, Rm 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993. **Refer to the Unique Identification Number 281360 when replying.** If you have any questions about the contents of this letter, please contact:: Ronald L. Swann, Chief, Dental, Ear, Nose, Throat, and Ophthalmic Devices Branch at the Food and Drug Administration, 10903 New Hampshire Avenue, WO66-3534, Silver Spring, Maryland 20903, facsimile at (301) 847-8137.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,

Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: (b) (4)