March 16, 2020

Jogohealth, Inc.
℅ Maria Griffin
Official Correspondent
mdi Consultants, Inc.
991 US Highway 22 West, Suite 200
Bridgewater, New Jersey 08807

Re: C190098
Product Name: JOGO-Gx
Dated: August 9, 2019
Received: August 12, 2019

Dear Maria Griffin:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the JOGO-Gx. Based on the information provided in your submission, we believe that the JOGO-Gx falls within 21 CFR 882.5050, Biofeedback Device, under product code HCC. A Biofeedback Device is a Class II type device, exempt from the premarket notification [510(k)] requirements of the Act, subject to the limitations to the exemption found in 21 CFR 882.9.

It is your responsibility to ensure compliance with all applicable requirements under the Act and FDA regulations. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; Medical Device Reporting requirements (21 CFR Part 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call 301-796-7400.

Please be advised that this decision does not mean that the Food and Drug Administration (FDA) has made a determination that your product complies with other requirements of the Act and FDA regulations or any Federal statutes and regulations administered by other Federal agencies.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents FDA's best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. FDA's response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions regarding this letter, please contact Heather Dean, Ph.D., Acting Assistant Director, Acute Injury Devices, at 240-402-9874.

Sincerely,

Michael J. Hoffmann -S

for Carlos Pena, Ph.D., M.S.
Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health