DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Physioware International
% MDI Consultants, Inc.
Ms. Maria F. Griffin
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

APR 15 2009

Re: K083492
Trade Name: PhysioWare International Low Energy Neurofeedback System (LENS)
Classification Regulation Name and Number: Biofeedback Device 882.5050
Regulatory Class: Class II Exempt
Product Code: HCC
Dated: March 11, 2009
Received: March 13, 2009

Dear Ms. Griffin:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 882.5050. Your device's classification regulation name, regulatory class and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 882.9. to determine whether or not your new device meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Ms. Geeta Pamidimukkala at geeta.pamidimukkala@fda.hhs.gov or the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

For Patricia Rumsey D.D.S.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Device's and
Radiological Health