DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2017

Wheelchair Fitness Solution
Alan Jacobs
President
4400 N Federal Highway
Suite 210-37
Boca Raton, FL 33431

Re: C170039
Product Name: Wheelchair Fitness Solution
Dated: March 29, 2017
Received: April 13, 2017

Dear Alan Jacobs:

Pursuant to Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), you requested information regarding the regulatory requirements applicable to the Wheelchair Fitness Solution under the Act. Based on the information provided in your submission, we have determined that the Wheelchair Fitness Solution is a general wellness product. In accordance with our guidance[1], CDRH defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use as defined in the guidance, and (2) present a low risk to the safety of users and other persons. A general wellness product, for purposes of the guidance, has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

Our determination that the Wheelchair Fitness Solution is a general wellness product is based on the following information provided in your submission: (i) the intended use of the product is to allow disabled individuals to train his or her full upper body from a wheelchair; (ii) the system is non-powered and includes a harness for the wheelchair. Therefore, we do not intend to enforce any applicable regulatory requirements under the Act, including premarket notification, and its implementing regulations for the Wheelchair Fitness Solution.

Please be advised that if you claim an intended use for the Wheelchair Fitness Solution other than those stated above, including using powered components or functional restoration, the

[1] See "General Wellness: Policy for Low Risk Devices" at p. 2-3. This guidance document is available for review at the following link: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf.

determination could change based on such revisions to your intended use and FDA may need to enforce regulatory requirements under applicable provisions of the Act.

Please note, however, that the Wheelchair Fitness Solution may be regulated by the Consumer Product Safety Commission (CPSC) as a consumer product. For information regarding CPSC laws and regulations, you may visit their web site at www.cpsc.gov.

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

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 requirements of any Federal statutes and regulations administered by other Federal agencies.

If you have any further questions regarding this letter, please contact Dr. Vivek Pinto, Chief, Physical Medicine and Rehabilitation Devices Branch (PMDB), Office of Device Evaluation, at 301-796-1136 or vivek.pinto@fda.hhs.gov, or for general questions, please contact the Division of Industry and Consumer Education at its toll free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration