Dynavision International LLC 9/5/17

MDRHO, Division 1
One Montvale Ave.
Stoneham, MA 02180

September 5, 2017

WARNING LETTER
CMS # 525321

VIA UNITED PARCEL SERVICE

Mr. James Phillip Jones
Chief Executive Officer
Dynavision International, LLC
8800 Global Way
West Chester, OH 45069-7070

Dear Mr. Jones:

During an inspection of your firm located in West Chester, Ohio,on April 18-26, 2017, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is the specification developer and complaint handling unit for the Dynavision D2 product, which is an attention task performance recorder. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), this product 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.

FDA has reviewed your firm's current website (www.dynavisioninternational.com/) as noted in the below examples and determined that the Dynavision D2 device is adulterated under section 501(f)(1)(B) of the Act, 21 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), for the device as described and marketed. The Dynavision D2 device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution of this device with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR § 807.81(a)(3)(ii).

Specifically, the previous model, Dynavision 2000, was cleared under K911938 with the indication for use stated as "measurement of reaction time." However, your firm's promotion of the device provides evidence that the device is intended for a number of indications not cleared under this 510(k), which would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval. Any therapeutic or rehabilitation claims and/or any diagnostic claims beyond the measurement of reaction time constitute a new intended use and require submission of a 510(k) prior to marketing of the device for such claims. This includes any rehabilitation claims related to stroke. Examples include:

Therapeutic claims relate to:

- Stroke
    - Cognitive Impairment including Deficits in Attention
    - Physical Impairment including Hemiplegia or Hemiparesis, and muscle pain
    - Psychosocial Factors including Anxiety and Depression
    - Visual Impairment including Hemispatial Neglect and Homonymous Hemianopsia
- Traumatic Brain Injury (TBI)
- Visual-motor and other neurocognitive conditions
- Parkinson's Disease
    - Physical Impairments including Resting Tremors
    - Gait Disturbances
    - Psychosocial Factors including Increased Risk of Depression
    - Visual Impairment
    - Cognitive Impairment including Deficits in Executive Function, Memory, and Attention
- Driver Rehabilitation
- Fall Prevention

Diagnostic claims that exceed the cleared diagnostic claims related to the measurement of reaction time:

- Neuro-Cognitive Evaluation for Concussion Management
    - Including recommended clinical interpretations related to "Return to Play" decisions.

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 C.F.R. § 807.81(b)). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm)**. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that Dynavision International, LLC immediately cease activities that result in the misbranding or adulteration of the Dynavision D2 device, such as the commercial distribution of the device for the uses discussed above.

This inspection also revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a

response dated May 13, 2017, from Dennis Roark, Customer Service Manager, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (FDA 483), that was issued to your firm on April 26, 2017. We address the response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.

Specifically, there are no written purchasing control procedures; no requirements, including quality requirements have been established for your suppliers; and you have not evaluated your suppliers. For example, you have not established requirements or evaluated the firm that contract manufactures your Dynavision D2 devices; and you have not established requirements or evaluated the software contract engineer, who makes the Dynavision D2 device's software changes.

The response dated May 13, 2017, is not adequate. Your response states that you will establish written purchasing control procedures by July 1, 2017. It does not address establishing specifications, including quality specifications for your suppliers, especially your contract manufacturer and your software contract engineer.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a)(1). Specifically, your firm assumed design control responsibilities and began making design changes to the Dynavision D2 device in July of 2011. The "DESIGN CONTROLS" procedure, DYN-OP-Design Controls-01, dated 5/24/13 is not adequate, specifically:

a. Failure to establish and maintain a Design History File (DHF) for Dynavision D2 device, as required by 21 CFR 820.30(j). Specifically, the DHF is incomplete in that there are no documented inputs, verifications, or validations for the current Dynavision D2 design.

b. Failure to perform a risk analysis for the Dynavision D2 device, as required by 21 CFR 820.30.

c. Failure to establish and maintain adequate procedures for the identification, documentation, validation, or where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

Specifically, the "VALIDATION AND CONTROL OF COMPUTER SOFTWARE" procedure, #DYN-OP-VDC-01, dated 5/24/13, has not been implemented, and there is no validation for the software revisions you have made to the Dynavision D2 since 2011.

The response dated May 13, 2017, cannot be assessed at this time. Your response states that you will contract a consultant to build the appropriate DHF; create a DFMEA and a formal risk analysis compliant to ISO-14971; and create a formal software validation process, including a controlled document adequately track all software revisions along with implementation dates. Your response states these corrective actions will be completed by July 1, 2017.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen working days from the date you receive this letter of the specific steps that you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) 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 15 working days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

If you have questions regarding any issues in this letter, please contact Compliance Officer, at or at . Please send your reply electronically to Joseph Matrisciano, Jr., Program Division Director, at **Joseph.Matrisciano@fda.hhs.gov (mailto:Joseph.Matrisciano@fda.hhs.gov)**.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in FDA 483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,
/S/
Joseph Matrisciano, Jr.
District Director
Office of Medical Device and Radiological Health Operations
Division 1/East

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)