DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

November 18, 2015

UPS EXPRESS MAIL

Mr. Wendell E. Dawson
President and Chief Executive Officer
ARK Bio-Medical Canada Corp.
P.O. Box 220
Winsloe, Prince Edward Island
Canada C1E 1Z2

Dear Mr. Dawson:

The United States Food and Drug Administration (FDA) conducted an inspection of ARK Bio-Medical Canada Corp., located at 671 Russtico Road, Route #7, North Milton, Prince Edward Island, Canada, from July 14 through July 17, 2015. During the inspection, the FDA investigator documented that your firm manufactures the ARK Bio Microwave Plasma Defroster. 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.

The inspection revealed that your device is 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, its manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

The significant deficiencies observed during the inspection include, but are not limited to, the following:

1. You failed to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100.

2. You failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198.

3. You failed to establish and maintain 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).

4. You failed to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures, as required by 21 CFR 820.20(c). Specifically, management reviews have not been conducted as described by your standard operating procedure (SOP) AB-QPR-001 entitled "Quality Procedures – Management Review". Your SOP specifies that management reviews will be conducted (b) (4) ; however, there is no documentation of management reviews being performed over the last several years.

5. You failed to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. Specifically, quality audits have not been conducted as described by your SOP AB-QPR-012 entitled "Quality Procedures – Quality Audits". Your SOP specifies that quality audits will be performed (b) (4) per year; however, no audits have been performed over the last several years.

6. You failed to establish and maintain procedures to ensure that equipment is routinely calibrated and maintained, as required by 21 CFR 820.72.

We acknowledge receipt of your written response dated August 13, 2015, which addresses the inspectional observations on the Form FDA 483 issued at the close of the inspection. We have reviewed your response and have the following specific comments. The items are numbered to correspond to the observations listed on the Form FDA 483.

Form FDA 483 observations #1 - #5

Your response states that you are taking steps to satisfy the requirements of the Quality System regulation, and that you will forward a completed copy of your new QA Manual with updated procedures once completed; however, your response does not provide sufficient detail on how you plan to address the specific observations cited on the Form FDA 483, or a timeframe for completion of your corrective actions.

We acknowledge your commitment to engage an external consultant to perform an independent audit of your QA system once you have completed your revisions to the QA Manual and performed an internal audit.

Form FDA 483 observation #6

Your response indicates that the (b) (4) Meter SN (b) (4) , and back-up (b) (4) (b) (4) Meter SN (b) (4) , have been calibrated, and you provided us with the Certificates of Calibration; however, your response does not describe your planned corrective actions to address your failure to establish and maintain procedures to ensure that all equipment is routinely calibrated and maintained.

We have reviewed a copy of the ARK Bio Microwave Plasma Defroster product brochure collected during the inspection. The brochure includes the statements "New ARK Bio Microwave Plasma Defroster" and "New units have the following new features". Please provide a detailed description of how the current Model 72 ARK Bio Microwave Plasma Defroster differs from the WesLabs Model 601 Blood Plasma Warming Device, which was the subject of the original premarket notification [510(k)] submission (BK870009).

Neither this letter, nor the observations listed on the Form FDA 483 presented to you at the conclusion of the inspection, are intended to be an all-inclusive list of deviations that may exist at your facility. It is your responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Please notify this office in writing of the specific steps you have taken or will take to address the noted violations and to prevent their recurrence. Your response should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, Building 71, Silver Spring, MD 20993. If you have any questions regarding this matter, you may contact Anna M. Flynn at (240) 402-9156.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research