FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

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FDA/MCH/MDD/DU2/20/0273

21st April 2020

The Business Head
Artemis Sciences Limited
P.O. Box Ct 1147
Cantonments
Accra

Tel: 0302243335/0544314665

Dear Sir,

RE: REGISTRATION OF MEDICAL DEVICES

This is to inform you that the Food and Drugs Authority (FDA) has completed the review of your medical device application for the registration of **GRADIAN AHP300 COMPREHENSIVE CARE VENTILATOR** pursuant to Section 118, Part 7 of the Public Health Act, 2012 (Act 851).

A conditional approval status has been granted to your application and the medical device has been issued with registration number **FDA/D.20-4056** which is valid for **one (1) year** and expires on **May 1, 2021**.

The registration validity will be extended and a certificate of registration issued after the under-listed queries have been addressed.

Submit a manufacturing license from a competent certifying Authority in the country of origin of the device.

1. Pay an amount of GH¢1,200 as fees for on-site testing of the device at your facility. This would be conducted on the installed and commissioned device.

   You are also to include in your letter, the name and telephone number(s) of the contact person as well as the location address of the site where the device would be installed.

2. Submit the under-listed documents and also make available on site the following documents to the FDA team:

   i. Standards For Calibration
   ii. Calibration Procedure
   iii. Operational Manual
   iv. Installation Qualification
   v. Operation qualification
   vi. Performance qualification

The conditions which apply to this approval are as follows:

- The medical device must conform to all the details submitted in your application and as modified in subsequent correspondence.
- The product cannot be advertised via promotional material/product launch unless the advertisement has been vetted and approved by the FDA, after the final approval has been granted.
- No changes may be made to the intended uses of the medical device without prior approval from the FDA.
- Importation of the product is not permitted after the period of validity of the registration has expired.

Post Market Surveillance activities into the quality of the product is on-going and any adverse findings will be brought to your immediate attention and the necessary regulatory measures taken.

You are also requested to actively monitor the safety of the product and report all adverse events to the FDA.

Please ensure that you promptly communicate any change in the safety information on the product to the FDA.

Yours faithfully,

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER

cc: Allied Healthcare Products Inc 1720 Sublette Avenue, St Louis Missouri 63110 USA

All FDA Regional Offices

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