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

April 9, 2014

Allied Healthcare
C/O John Smith, M.D., J.D., Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, D.C. 20004

Re: K131098
Trade/Device Name: AHP300P Emergency Portable Ventilator
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: March 18, 2014
Received: March 18, 2014

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

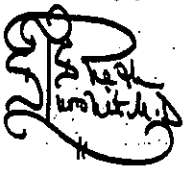
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allied HEALTHCARE PRODUCTS INC.

Quality Assurance / Regulatory Affairs
1720 Sublette Avenue * St. Louis, MO 63110
Telephone: 314-771-2400 * Fax 314-268-1767

Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: AHP300P, EMERGENCY PORTABLE VENTILATOR

Indications for Use: The AHP300P is intended to be used as an electrically controlled emergency ventilator that requires an external compressed gas source. This ventilator is designed to provide emergency respiratory support by means of a face mask or tube inserted into the patients airway. The ventilator is intended for use on patients weighing greater than 5kg (11 lbs). The ventilator is intended to be used in the environments associated with emergency medical services (EMS), inter-hospital transport and hospital facilities usage. The ventilator is intended to be used in temperatures of -18 C to 50 C (0 F to 122 F) and 5% to 95 % relative humidity non-condensing.

Prescription Use: Yes and/or Over-the-Counter Use: No

(Part 21 CFR 801 Subpart D) (Part 21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K131098

Anya C. Harry -S
2014.04.08
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