DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. George L. Small
AirSep Corporation
290 Creekside Drive
Amherst, NY 14228

Re: K962766
AirSep Impulse Oxygen Conserving Device
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. Small:

This letter corrects our substantially equivalent letter of October 10, 1996, regarding the AirSep Impulse Oxygen Conserving Device. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NFB as indicated above.

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 INTENDED USE

The AirSep Impulse Oxygen Conserving Device is to be normally used in a home or institutional environment by persons who suffer from various forms of Chronic Obstructive Pulmonary Disease (COPD). It is to be used only when a nasal oxygen cannula is prescribed.

The Impulse has been designed to work in conjunction with a portable, regulated flow bottled oxygen source. The unit can be used with any oxygen source capable of delivering gaseous oxygen at 20 to 25 psig. Oxygen is delivered in a precise amount at the optimum point in the breathing cycle through the nasal cannula. This form of delivery maximizes the beneficial effects of supplemental oxygen while eliminating unnecessary waste, thus increasing user mobility and ambulatory duration of the user.

The Chad Therapeutics Oxymatic Electronic Oxygen Conserver Model 301 is a legally marketed predicate device with the same intended use.

The AirSep Impulse differs from the CHAD Oxymatic in having an alarm to signal no inspiration if no breaths are detected during a 30 second time period. This difference does not adversely affect the safety and effectiveness of the device.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K962766

X prescription use