DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1997

Blake M. Paterson, M.D.
Arbor Research Corporation
806 Airport Boulevard
Ann Arbor, Michigan 48108

Re: K971129
OxyPure Portable Oxygen Generator
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: March 25, 1997
Received: March 27, 1997

Dear Dr. Paterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number: K971129

Device Name: OxyPure Portable Oxygen Generator

Indications For Use:

Oxygen generated by a portable oxygen generator is supplemental and should not be considered life-supporting. Supplemental oxygen is non-addictive but should only be used at the specific liter flow and number of hours prescribed by your physician.

This device is intended for home use, in patients requiring supplemental oxygen for the palliative or therapeutic treatment of a variety of respiratory diseases, including emphysema, chronic obstructive pulmonary disease, cardiopulmonary insufficiency and bronchiectasis.

Federal law restricts this device to sale by or on the order of a licensed physician, and is to be prescribed only after appropriate clinical evaluation or oximetry screening tests have been performed on the patient by the prescribing physician.

This unit is not to be used for or with any life-supporting applications. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this machine may require additional monitoring. In the event of an alarm or if you are experiencing any signs of patient discomfort, consult your physician immediately.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard N. Phillips

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971129

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**