DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Ms. Marge Walls-Walker
Regulatory Affairs
Ventlab Corporation
2934 Highway 601 North
Mocksville, NC 27028

Re: K013308
Ventlab Hyperinflation Bag System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NHK

Dear Ms. Walls-Walker:

This letter corrects our substantially equivalent letter of December 20, 2001, regarding the Ventlab Hyperinflation Bag System. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NHK 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

## Indications for Use:

**510k Number :** K013308

**Applicant:** Ventlab Corporation

**Device Name:** Ventlab Hyperinflation Bag System

Ventlab Corporation's Hyperinflation Bag System is a pulmonary-assist device intended to provide controlled or assisted ventilation to patients. It is designed for patients suffering from respiratory insufficiency. The system's mode of operation is to hyper-ventilate a patient by forcing a volume of fresh gas into the patient via compression of the reservoir bag. Typical treatment consists of hyper-inflating the patient's lung(s) over several respiration cycles. The operating clinician controls peak pressure and monitors pressure in the lungs by means of a user-supplied manometer.

Federal (USA) law restricts this device to sale by or on the order of a physician.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-The-Counter Use**_____

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