



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 1997

Mr. Damon R. Lawson
Marketing Manager
Allied Healthcare Products, Inc.
Ventilation Products Division
2085 Rustin Avenue
Riverside, California 92507-2437

Re: K972203
BEAR® Adjustable Pressure Limit Valve
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: September 17, 1997
Received: September 19, 1997

Dear Mr. Lawson:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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, Ph.D.

Director

Division of Cardiovascular,

Respiratory, and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosures

K972203

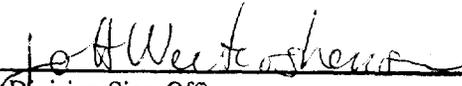
BEAR[®] Adjustable Pressure Relief Valve

Statement of Intended Use:

The BEAR Adjustable Pressure Limit Valve is intended to be an accessory for the BEAR 33 Volume Ventilator which provides clinically accepted features for the ventilation management of pediatric patients requiring breath volume delivery of 100 ml to 2200 ml.

In addition to the standard features, the intent of this device is to be utilized during high flow and high tidal volume delivery to those patients with an uncuffed artificial airway or in other patient configurations which ensure an intentional artificial airway leak.

The pressure relief valve is intended to be used with patients that have respiratory failure/insufficiency and require mechanical ventilation.


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972203

prescription use

OTC