K992788

SEP 16 1999

510(k) Summary
BEAR Cub 750 PSV Infant Ventilator

Bear Medical Systems, Inc.
1100 Bird Center Drive
Palm Springs, California 92262

Contact:
Neil Battiste
Phone Number (760) 778-7341
FAX (760) 778-7288

Date: August 13, 1999

1.	TRADE/PROPRIETARY NAME:	BEAR Cub 750 PSV Infant Ventilator
	CLASSIFICATION NAME:	Ventilator, Continuous (Respirator)
	COMMON/USUAL NAME:	Neonatal/Infant Ventilator
2.	ESTABLISHMENT REGISTRATION NUMBER:	2022747
3.	PRODUCT CLASSIFICATION	Class II
4.	ANESTHESIOLOGY DEVICE CLASSIFICATION PANEL (73 CBK)	

Predict Device

Siemens Servo 300 A Ventilator	(K970839)
V.I.P. Bird Ventilator	(K895541)
Baby Log 8000 Plus Ventilator	(K974176)

Device Description

The BEAR CUB 750 PSV Infant ventilators is a modification from the BEAR CUB 750 vs. The BEAR CUB 750 PSV Infant ventilators incorporate all previous (3) three modes with the addition of (4) four new modes. The additional modes are, Flow Cycle Assist Control, Flow Cycle SIMV, SIMV/PSV, and PSV. The BEAR CUB 750 PSV Infant ventilators incorporate all previous function for the Bear Cub 750vs with the addition of, digital PEEP, monitored inspired tidal volume, a low minute volume alarm, an audible silence for the volume limit, CPAP/PSV back up function and the Low Inspiratory Pressure threshold was changed to a calculated threshold function.

Statement of Intended use:

The BEAR CUB 750 PSV Infant Ventilator is intended to provide clinically accepted features for the ventilation management of a patient population ranging from the small neonate (500 grams and larger) to a small pediatric patient (up to 30 kilograms).

The etiologies to which these devices may be applied consistent with current clinical practices include:

Hyaline Membrane Disease
Respiratory Distress Syndrome
Low Surfactant Syndrome
Chronic Lung Disease of the Neonate/Pediatric Patient
Neurological Impairment
Pulmonary Hypoplasia
Persistent Pulmonary Hypertension
Meconium Aspiration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1999

Mr. Darryl L. Shelby
Bear Medical Systems, Inc.
1100 Bird Center Drive
Palm Springs, CA 92262

Re: K992788
BEAR Cub 750 PSV Infant Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: August 11, 1999
Received: August 19, 1999

Dear Mr. Shelby:

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 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). 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/dsma/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

Statement of Intended use:

The BEAR CUB 750 PSV Infant Ventilator is intended to provide ventilatory support for a patient population ranging from the small neonate 500 grams and larger to a small pediatric patient up to 30 kilograms.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992786

✓ Prescription Use — OTC