K082724
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Newport MEDICAL

DEC 16 2008

510(k) Summary

NEWPORT HT50® Ventilator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information: Newport Medical Instruments, Inc.
1620 Sunflower Avenue
Costa Mesa, CA 92626

Contact Person: Dana Rodriguez
Vice President, RAQA

Summary Date: 16 December 2008

II. Device Name

Proprietary: NEWPORT HT50® Ventilator
Models HT50-H, HT50-HB, HT50-H1, and HT50-H1B

Common: Continuous Ventilator

Classification: II

Product Code: CBK

CFR Section: 868.5895

III. Predicate Device

The predicate devices for modified NEWPORT HT50 Ventilator are:

- NEWPORT HT50 Ventilator cleared under K992133;
- Pulmonetic Systems LTV 1000 cleared under K981371, K984056, K002881, K010608, K032226, K040540, and K051767); and
- Versamed Medical Systems iVENT201 cleared under K981668, K011957, K021981, K042468, K052554, K053270, K061627.

IV. Device Description

The modified NEWPORT HT50 Ventilator is an electrically powered, microprocessor controlled, variable flow generating ventilator which provides Assist Control, SIMV and SPONT/CPAP modes of ventilation in combination with servo-solenoid-controlled, built-in PEEP.

The modified NEWPORT HT50 may be powered by external power (100-240 VAC or 12-30 VDC) or internal battery system power. Any time external power is connected to the ventilator, the internal battery system is charging.

V. Intended Use

This modified NEWPORT HT50 is intended to provide continuous or intermittent mechanical ventilator support for the care of individuals who require mechanical ventilation. Specifically, the NEWPORT HT50 is applicable for adult and pediatric (i.e. infant, child and adolescent) patients, greater than or equal to 10 kg (22 lbs), who require the following general types of ventilatory support: positive pressure ventilation with Assist/Control, SIMV and SPONT/CPAP modes of ventilation.

The modified NEWPORT HT50 is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.

VI. Technological Characteristics

The modified NEWPORT HT50 combines a secondary, internal, back-up Nickel-Metal Hydride (NiMH) battery with an independent charging system with the existing Lead Acid (LA) internal battery and charging system, thereby creating the DUAL PAC™ Internal Battery system. When the primary internal LA battery charge level reaches the low battery threshold, the Low Battery alarm activates (message, LED indicator and audible alarm). The unit will automatically add in the power of the secondary NiMH battery and both batteries will continue to power the ventilator and the alarms for a minimum of 30 minutes before shut down. This alarm message (Low Battery), the blinking LED indicator and audible alarm give notice that a minimum of 30 minutes remains to find an alternate power source before the unit will shutdown. When the combined battery power reaches the battery empty threshold, a Battery Empty alarm is activated (message, LED indicator and audible alarm) alerting the user that there is a minimum of 15 minutes to shut down. Ensuring these defined time periods for battery life increases the margin of safety for battery usage.

VII. Device Testing

Testing supporting transport use of the device was based on the following standards:

- MIL-STD-810E *Environmental Test Methods and Engineering Guidelines*
- IEC 68-2 *Environmental Testing*

Testing for the DUAL PAC Internal Battery design encompassed validation and verification of the new design, re-verification of all functional and alarm aspects, and EMC and safety testing; this testing is summarized following:

A. <u>Validation and Verification of New Design</u>

The battery pack and charging circuits were tested to verify functionality, including:

- Correct switching to back-up battery at target voltage;
- Proper charging circuit function;
- Ventilator operation on main battery and back up battery;

- Verification of proper warnings;
- Verification of proper switching to back up battery if main battery is defective; and
- Verification of proper warning to user in the event that back up battery is defective.

B. Re-Verification of All Functions and Alarms

The NEWPORT HT50 was tested to ensure proper functionality and alarming for ventilator operations. This complete re-verification of all functions/alarms assured that software revisions associated with the DUAL PAC Internal Battery system did not inadvertently affect any ventilator function or alarm.

C. EMC and Safety Testing

Testing was also performed to assure that the ventilator with the new battery pack configuration meets electrical safety, environmental, and EMC requirements.

VIII. Clinical and Animal Testing

No clinical or animal data were included in this submission.

IX. Conclusions

All testing demonstrates that the modified NEWPORT HT50 Ventilator performs as intended and is therefore suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

Ms. Dana Rodriguez
Vice President of Regulatory Affairs and Quality Assurance
Newport Medical Instruments, Incorporated
1620 Sunflower Avenue
Costa Mesa, California 92626

Re: K082724
Trade/Device Name: NEWPORT HT50® Ventilator Models HT50-H, HT50-HB, HT50-H1, and HT50-H1B
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU
Dated: September 15, 2008
Received: September 17, 2008

Dear Ms. Rodriguez:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082724

Device Name: NEWPORT HT50® Ventilator
Models HT50-H, HT50-HB, HT50-H1, and HT50-H1B

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082724