

K111146

DEC - 1 2011



Breathing care into all we do.

510(k) Summary

Newport HT70™ Ventilator

- I. Submitter Information:** Newport Medical Instruments, Inc.
1620 Sunflower Avenue
Costa Mesa, CA 92626
- Contact Person: Tom Colonna
Director, RA/QE
- Summary Date: 18 July 2011
- II. Device Name**
- Proprietary: Newport HT70®
- Common: Ventilator, Continuous, Facility Use;
Ventilator, Continuous, Home Use
- Classification: II
- Product Code: CBK; NOU
- CFR Section: 868.5895
- III. Predicate Devices**
- The HT70 is substantially equivalent to the following legally marketed predicate devices:
- NEWPORT HT70® Ventilator cleared under K090888;
 - CareFusion LTV® 1200 cleared under K060647;
 - Versamed Medical Systems iVENT™ 201 cleared under K073694.
- IV. Device Description**
- The Newport HT70 Ventilator provides ventilatory support for neonate, infant, pediatric and adult patients. It can be used in hospital, sub-acute, emergency response, transport and homecare environments under the direction of a physician. The HT70 ventilator design provides maximum mobility and safety for short or long distance transport of critically ill patients and also for patients who are going about their normal activities of daily life.

The HT70 may be operated from AC or DC external power sources or from the integrated battery system. Any time the ventilator is connected to external power, the integrated battery system is charged, including while the ventilator is in use. The HT70 ventilator has A/CMV, SIMV and SPONT ventilatory modes (Pressure or Volume).

The controls of the HT70 ventilator are easily found on the front touch screen and panel. The touch screen can be set up in Hospital, Transport or Basic functional Domains to provide the user with full or limited access. The HT70 has a Trends screen for displaying data graphically. User Help screens present information for all controls and features.

V. Intended Use

The Newport HT70 family of ventilators is intended to provide continuous or intermittent positive pressure mechanical ventilatory support for the care of individuals who require mechanical ventilation through invasive or non-invasive interfaces. Specifically, the Newport HT70 family of ventilators is applicable for infant, pediatric and adult patients greater than or equal to 5 kg (11 lbs).

The Newport HT70 is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.

The Newport HT70 is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.

VI. Reason for the Submission

The purpose of this traditional 510(k) is to request authorization for enhancement to the Newport HT70 ventilator to include the following features:

- On-airway flow sensor for exhaled volume monitoring and flow trigger
- SpO₂ monitoring using a cleared accessory device.

The Newport HT70 ventilator has been determined to be substantially equivalent to other legally marketed predicate ventilators. The HT70 ventilator is an extension of the current HT70 design and technology.

VII. Nonclinical Data

The Newport HT70 ventilator has undergone extensive verification, validation and design safety testing, all of which confirms that the device meets its design, performance, and safety requirements.

VIII. Conclusions

All testing demonstrates that the Newport HT70 performs as intended and has acceptable mechanical properties when used in accordance with its labeling; the device is therefore suitable for its intended use. As the device's intended use is comparable to the referenced predicate devices, and its operating principles, ventilation modes and performance parameters are comparable to the predicate devices, the HT70 is substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

DEC - 1 2011

Mr. Tom Colonna
Director, Regulatory Affairs/QE
Newport Medical Instruments, Incorporated
1620 Sunflower Avenue
Costa Mesa, California 92626

Re: K111146
Trade/Device Name: Newport HT70™ Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU
Dated: November 11, 2011
Received: November 14, 2011

Dear Mr. Colonna:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

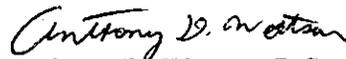
Page 2 – Mr. Colonna

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

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): K111146

Device Name: Newport HT70™ Ventilator

Indications for Use:

The Newport HT70 family of ventilators is intended to provide continuous or intermittent positive pressure mechanical ventilatory support for the care of individuals who require mechanical ventilation through invasive or non-invasive interfaces. Specifically, the Newport HT70 family of ventilators is applicable for infant, pediatric and adult patients greater than or equal to 5 kg (11 lbs).

The Newport HT70 is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.

The Newport HT70 is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.

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

Page 1 of 1

510(k) Number: K111146