K121891

Newport MEDICAL

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NOV 9 2012

510(k) Summary

AURA Ventilator

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

Contact Person: Tom Colonna
Senior Director, Regulatory Affairs

Summary Date: 10 October 2012

II. Device Name

Proprietary: AURA

Common: Ventilator, Continuous, Facility Use;
Ventilator, Continuous, Home Use

Classification: II

Product Code: CBK; NOU

CFR Section: 868.5895

III. Predicate Devices

The AURA is substantially equivalent to the following legally marketed predicate devices:

- NEWPORT HT70® Ventilator cleared under K090888, K111146
- NEWPORT e360 cleared under K053502, K101803

IV. Device Description

The AURA Ventilator provides ventilatory support for infant, pediatric and adult patients. The AURA ventilator is a prescription device that can be used in hospital, sub-acute, emergency response, transport and homecare environments under the direction of a physician.

The AURA ventilator 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 AURA ventilator has A/CMV, SIMV, SPONT and VTPC ventilatory modes (Pressure or Volume).

The controls of the AURA 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 AURA has a Trends screen for displaying data graphically. User Help screens present information for all controls and features. The AURA family of ventilators has models that can be differentiated based on whether or not the device has SpO_2 monitoring capability.

V. Intended Use

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

The AURA ventilator is a restricted medical device intended for use by qualified, trained, personnel under the direction of a physician. The AURA ventilator 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 to market the AURA ventilator. The AURA ventilator includes the following features:

- A QuickStart feature for users to set-up the ventilator
- Message for the evaluation of possible weaning

The AURA ventilator has been determined to be substantially equivalent to other legally marketed predicate ventilators. The design and technology of used for the AURA ventilator are common to the HT70 ventilator.

VII. Nonclinical Data

The AURA ventilator has undergone extensive verification, validation and design performance safety testing, all of which confirms that the device meets its design, performance, and electrical safety requirements. The following testing was completed to verify the performance of the AURA ventilator:

Volume Control
Pressure Support Pressure Control
Trigger Function
PEEP/Bias Flow
Flow Patterns
Air/Oxygen Entrainment/Monitoring
Screens
Waveforms
Power Performance
Intake Valve/Exhalation Resistance

Respiration Rate, Inspiration time & I/E Ratio
Functional Safety
Alarms
Endurance
O_2 Cylinder Time Monitoring
SpO_2 Monitoring
Battery Time Monitoring
Volume Target Pressure Control (VTPC)
SIMV
Export Data
Maintenance Due
Usability Test on Less Trained Users
Emergency/Transport and Environmental Safety
Shipping Container

VIII. Conclusions

Verification and validation activities were conducted to establish the performance and safety characteristics of the Aura ventilator. All testing demonstrated that the AURA ventilator 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, operating principles, ventilation modes and performance parameters are comparable to the referenced predicate devices. Therefore, the AURA ventilator is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 9, 2012

Mr. Tom Colonna
Senior Director, Regulatory Affairs
Newport Medical Instrument, Incorporated
1620 Sunflower Avenue
Costa Mesa, California 92626

Re: K121891
Trade/Device Name: AURA Family of Ventilators
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK; NOU
Dated: October 10, 2012
Received: October 12, 2012

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.

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" (21CFR 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,

Kwame O. Ulmer

Digitally signed by Kwame O. Ulmer
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=1300183618
Date: 2012.11.09 15:45:48 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K121891

Device Name: AURA Family of Ventilators

Indications for Use:

The AURA Family of Ventilators is intended to provide continuous or intermittent positive pressure mechanical ventilatory support through invasive or non-invasive interfaces to individuals that require such medical care. Specifically, the AURA Family of Ventilators is applicable for infant, pediatric and adult patients greater than or equal to 5 kg (11 lbs.).

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

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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

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