K101803

SEP 0 8 2010

510(k) Summary

Newport e360™ 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.

The term "substantial equivalence" as used in this Premarket Notification is limited to the definition found in the Federal Food, Drug, and Cosmetic Act, 21 CFR 807, Subpart E, and relates only to whether the proposed device may be marketed without prior reclassification or clinical approval. This submission is therefore not related to the coverage of any patent and is not to be interpreted as admission or used as evidence in a patent infringement law suit or any other patent matters. [Reference Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355).]

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

Contact Person: Tom Colonna
Director, RAQA

Summary Date: 21 June 2010

II. **Device Name**

Proprietary:	Newport e360™ Ventilator
Common:	Ventilator, Continuous, Facility Use
Classification:	II
Product Code:	CBK
CFR Section:	868.5895

III. **Predicate Devices**

The e360 is substantially equivalent to the following legally marketed predicate devices:

- Newport e360 Ventilator, K053502;
- Newport e500 Wave Ventilator, K030780, K061094

IV. Device Description

The Newport e360 Ventilator is a pneumatically powered, microprocessor controlled ventilator. Performance characteristics and clinical features support infant/pediatric (≥20 mL) through adult patients. Front panel controls allow trained operators to select ventilation controls for volume control, pressure control and volume target pressure control breath types in A/CMV, SIMV and SPONT modes. A comprehensive alarm system is built-in to alert the user to violations of preset safety limits. When fully charged, the internal battery provides approximately 45 minutes of power. The alarms associated with the e360 meet or exceed standards of critical care ventilators and have been developed in compliance with the FDA Draft Reviewer Guidance for Ventilators (1995). The alarms of the e360 span both technical (ventilator related) alarms and non technical alarms (patient related alarms).

V. Intended Use

The e360 Ventilator is intended to provide continuous (ET tube) or non-continuous (mask) ventilatory support and monitoring for infant, pediatric, and adult patients with a tidal volume of ≥ 20 mL. The device is prescription use only. The intended environments include hospital, hospital-type, and intra-hospital transport environments. Hospital use typically includes general care floors, operating rooms, special procedure areas, and intensive and critical care areas within the hospital. Hospital-type use includes facilities such as or similar to surgicenters, sub-acute centers, and special nursing facilities outside of the hospital. Intra-hospital transport includes patient transport within the hospital or hospital-type facility.

This is the same Intended Use as the previously cleared Newport e360 Ventilator (K053502).

VII. Nonclinical Data

The Newport e360 ventilator was subjected to a series of tests which verified the following changes:

- Flex Cycle option added to allow the Expiratory Threshold to adjust within a specific range to minimize the end-inspiratory pressure overshoot.
- Minor changes (did not affect safety, efficacy, intended use, principle of operation, or control mechanism of the e360) to the software and design which have been implemented incrementally since the initial release of the Newport e360 Ventilator.

All test results confirm the device to meet its current design, performance, and safety specifications.

VIII. Clinical Data

No clinical or animal data were included in this submission.

IX. Conclusions

All testing demonstrates that the Newport e360 performs as intended and has acceptable mechanical properties when used in accordance with its labeling; the device is therefore suitable for its intended use which is unchanged from the currently cleared version of the Newport e360 ventilator. 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 e360 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Tom Colonna
Director, Regulatory Affairs & Quality Engineering
Newport Medical Instruments, Incorporated
1620 Sunflower Avenue
Costa Mesa, California 92626

SEP 0 8 2010

Re: K101803
Trade/Device Name: Newport e360™ Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 6, 2010
Received: August 9, 2010

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.

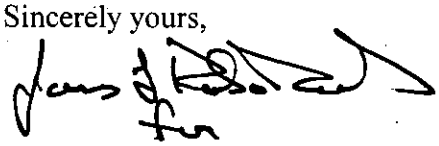
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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):

K101803

SEP 08 2010

Device Name: Newport e360™ Ventilator

Indications for Use:

The e360 Ventilator is intended to provide continuous (ET tube) or non-continuous (mask) ventilatory support and monitoring for infant, pediatric, and adult patients with a tidal volume of ≥ 20 mL. The device is prescription use only. The intended environments include hospital, hospital-type, and intra-hospital transport environments. Hospital use typically includes general care floors, operating rooms, special procedure areas, and intensive and critical care areas within the hospital. Hospital-type use includes facilities such as or similar to surgicenters, sub-acute centers, and special nursing facilities outside of the hospital. Intra-hospital transport includes patient transport within the hospital or hospital-type facility.

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)

L Schultheiss

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

510(k) Number: K101803