K992133

AUG 4 2000

NEWPORT MEDICAL INSTRUMENTS
Newport HT50 Ventilator 510(k) Submission

Section XV
510(k) Summary or 510(k) Statement

A. Submitter's Name and Address

Newport Medical Instruments, Inc.
760 West 16th Street
Costa Mesa, California 92627

Mailing Address:
P.O. Box 2600
Newport Beach, California 92658

B. Submitter's Phone and FAX Number
(949) 642 – 3910 Telephone
(949) 645 – 5026 FAX

C. Name of Contact Person

Karon Morell
Vice President, Quality Assurance & Regulatory Affairs

D. Date the Summary was Prepared

June 22, 1999

E. Name of the Device

1. Trade or Proprietary Name

Newport HT50 Ventilator

2. Common or Usual Name

Ventilator

3. Classification Name

Respiratory Ventilator

F. Summary of Substantial Equivalence

The Newport HT50 Ventilator, the TBird Legacy Ventilator and the Pulmonetics LTV1000 ventilator are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The performance and clinical features of each ventilator is to support pediatric (≥ 10 kg) through adult applications.

G. Description of the Device

The Newport HT50 Ventilator is a self-contained, electrically powered, microprocessor controlled ventilator. With performance characteristics and clinical features that can support pediatric (≥10 kg) through adult patients, the HT50 is the device of choice for use in sub-acute, emergency room and home care environments (P/N HT50-H) and for transport applications (P/N HT50-T).

Front panel controls allow trained operators to select between a number of operational modes, pressure support and volume or pressure control. A comprehensive alarm system is built-in to alert the user to violations of preset safety limits. When fully charged, the internal battery provides up to 10 hours of power. With its patented, self-contained gas supply source, the HT50 requires no external air compressor.

H. Device Intended Use

The device is intended to provide continuous or intermittent mechanical ventilator support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients, greater than 10 kg or 22 lbs., who require the following general types of ventilatory support, as prescribed by an attending physician: positive pressure ventilation and assist/control. SIMV, CPAP modes of ventilation. The ventilator is suitable for use in post-acute, emergency room, home care environments (P/N HT50-H) and for transport applications (P/N HT50-T). Transport application is only applicable to the HT50-T.

I. Summary of Comparison of Technological Characteristics

The HT50-H and HT50-T share substantial equivalency with the TBird Legacy ventilator and the Pulmonetics LTV1000 ventilator across the spectrum of the patient population (pediatric to adult) for which each was

designed. All of the devices share common modalities (volume control, pressure control, pressure support) and significantly overlap in the clinical range of function for their target population. Although some differences in design application are noted the essential clinical function of each device is significantly similar and mimics each other in the typical frame of use by the health care provider. Each provide significant safety features in terms of alarms, back up ventilation, and fail safe mechanisms. The HT50-T and Pulmonetics unit share significant functions in their use as transport units. Each provide internal battery, ease of use, simple circuit design and matching clinical function.

J. Summary of Nonclinical Tests

The Newport HT50 Ventilator meets all applicable device specification requirements for performance testing as identified in the FDA Reviewer guidance for ventilators and heated humidifiers.

K. Conclusion

The Newport HT50 Ventilator as a self-contained, electrically powered, microprocessor controlled ventilator has clinically and functionally proven to be safe and efficacious. With performance characteristics and clinical features that can support pediatric (≥10 kg) through adult patients, the HT50 is the device of choice for use in sub-acute, emergency room and home care environments (P/N HT50-H) and for transport applications (P/N HT50-T).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Ms. Susan Miller
Newport Medical Instruments, Inc.
760 West 16th Street, Building N
Costa Mesa, CA 92627

Re: K992133
Newport HT50 Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: May 11, 2000
Received: May 12, 2000

Dear Ms. Miller:

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,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992133

Device Name: Newport HT50 Ventilator

Indications for Use:

The device is intended to provide continuous or intermittent mechanical ventilator support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients, greater than 10 kg or 22 lbs., who require the following general types of ventilatory support, as prescribed by an attending physician: positive pressure ventilation and assist/control. SIMV, CPAP modes of ventilation. The ventilator is suitable for use in post-acute, emergency room, home care environments (P/N HT50-H) and for transport applications (P/N HT50-T). Transport application is only applicable to the HT50-T.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Division of Cardiovascular & Respiratory Devices

510(k) Number K992133

PRESCRIPTION USE X - OR - OVER-THE-COUNTER USE ____

(Optional Format 3-10-98)