K041406

DEC 15 2004

510(k) SUMMARY

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

A. Name, Address, Phone and Fax Number of the Applicant

Newport Medical Instruments, Inc.

760 West 16th Street, Building N

Costa Mesa, California 92627

Telephone: (949) 642-3910

Fax: (949) 645-5026

B. Contact Person

Richard Waters

Vice President, Regulatory Affairs / Quality Assurance

760 West 16th Street, Building N

Costa Mesa, California 92627

Telephone: (949) 642-3910

Fax: (949) 645-5026

C. Date Prepared

September 24th, 2004

D. Device Name

Newport C250 Air Compressor

E. Device Description

The Newport C250 Air Compressor is electric and produces air from the normal environment to supply compressed air for Newport ventilators.

F. Device Intended Use

The Newport C250 Air Compressor is designed and manufactured to supply a source of clean, oil-free pressurized air at 42 psig for use with the E100M, E150, E200, and e500 Newport Ventilators.

G. Substantial Equivalence Summary

The Newport C250 Air Compressor is substantially equivalent in intended use, physical characteristics, performance, and safety characteristics to the Bird 6500 Air Compressor, cleared under #K864547; the Newport C100 Air Compressor and the Newport C200D Air Compressor. Both the Newport C100 and C200D Air Compressors are preamendment devices that were on the US market prior to May 28, 1976.

H. Device Testing

Comprehensive testing has been conducted on The Newport C250 Air Compressor in accordance with various industry recognized standards, including: IEC 60601-1-2:1993, CSA 22.2 No 601-1-M90, UL 2601-1, EN 55011:1998 &A1:1999. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2004

Mr. Richard Waters
Vice President, Regulatory Affairs/ Quality Assurance
Newport Medical Instrument, Incorporated
760 West 16th Street, Building N
Costa, Mesa, California 92627

Re: K041406
Trade/Device Name: Newport C250 Air Compressor Model 250
Regulation Number: 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI
Dated: November 16, 2004
Received: November 17, 4004

Dear Mr. Waters:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K041406

Device Name: Newport C250 Air Compressor Model 250

Indications for Use:

The Newport C250 Air Compressor is designed and manufactured to supply a source of clean, oil-free pressurized air at 42 psig for use with the E100M, E150, E200, and e500 Newport Ventilators.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K041406

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(Posted November 13, 2003)