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510(k) SUMMARY

JAN - 2 2009

LEVEL-5, INC.'S NEPTUNE HYPERBARIC VENTILATOR

Submitters Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: December 31, 2008

Name of Device and Name/Address of Sponsor

Neptune Hyperbaric Ventilator

Level-5, Inc.
8005 Shannon Industrial Park Lane
Atchison, KS 66002

Common or Usual Name

Ventilator, Continuous (respirator)

Classification Name

Continuous Ventilator (21 C.F.R. § 868.5895)

Product Code

CBK

Predicate Device

Sechrist Industries, Inc.'s Hyperbaric Ventilator Model 500A (K760852)

Indications for Use

The Neptune Hyperbaric Ventilator is indicated for use in patients in respiratory failure or who otherwise require mechanically supported ventilation during hyperbaric therapy.

Technological Characteristics

The Neptune Hyperbaric Ventilator consists of two main components: (1) a Control Module and (2) a Patient Breathing Circuit. The Control Module is exterior to the hyperbaric chamber and allows the operator to control oxygen flow to the patient. The Control Module houses pressure regulators and timing valves for control of inspiratory time, expiratory time, and inspiratory flow, as well as pressure gauges to monitor main regulator output pressure, hyperbaric chamber pressure, and timing valve control pressure. The Patient Breathing Circuit is located inside the hyperbaric chamber and includes an exhalation valve, a pressure relief valve, and a pressure gauge. The Patient Breathing Circuit is supplied with oxygen from the Control Module and returns interior chamber pressure values to the Control Module. Three high-pressure hoses connect these two components through the hyperbaric chamber door. The Patient Breathing Circuit is then attached to the patient's endotracheal tube for oxygen delivery. The Control Module and the Patient Breathing Circuit are components of the Neptune Hyperbaric Ventilator that are supplied with the device.

Safety features include a patient airway pressure gauge, adjustable pressure relief valve, and a hand-operated oxygen flush valve.

Performance Data

Performance testing was conducted that confirms that the device operates as designed. In all instances, the Neptune Hyperbaric Ventilator functioned as intended; delivery of the gas volumes, frequencies, and safety devices was verified.

Substantial Equivalence

The Neptune Hyperbaric Ventilator is as safe and effective as the Sechrist Hyperbaric Ventilator Model 500A. The Neptune Hyperbaric Ventilator has the same intended uses, similar technological characteristics, and similar principles of operation as its predicate device. The minor technological differences between the Neptune and its predicate device raise no new questions of safety or effectiveness. Thus, the Neptune Hyperbaric Ventilator is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 2009

Level-5, Incorporated
C/O Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington DC 20004

Re: K082351
Trade/Device Name: Neptune Hyperbaric Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 22, 2008
Received: December 22, 2008

Dear Mr. Holstein:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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 Statement

510(k) Number (if known) K082351

Device Name: Neptune Hyperbaric Ventilator

Indications for Use:

The Neptune Hyperbaric Ventilator is indicated for use with patients in respiratory failure or who otherwise require mechanically supported ventilation during hyperbaric therapy.

Prescription Use X (Part 21 C.F.R. 801 Subpart D) AND/OR Over-the -counter Use ___ (21 C.F.R. 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

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