K092263

510(k) SUMMARY JAN 21 2010
Providence Global Medical, Inc's
EnduraVent-5 Ventilator

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

Submitters Name: Helen Redd, President
Providence Global Medical, Inc.
4659 South 2300 East, # 203
Salt Lake City, UT 84117
Telephone: 800 292 8765
Contact Person: Helen Redd, President
Date Prepared: July 15, 2009

Name of Device and Name/Address of Sponsor

EnduraVent-5 Ventilator
Providence Global Medical, Inc.
4659 South 2300 East, # 203
Salt Lake City, UT 84117

Common or Usual Name

Ventilator, Continuous, Facility Use

Classification Name

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

Product Code

CBK

Predicate Device

Magellan Ventilator (K002951)

Indications for Use

The EnduraVent-5 Ventilator is indicated to provide mechanical ventilation for adults and pediatric patients (pediatrics greater than 9 kg body weight) during in-hospital transport only.

Technological Characteristics

The EnduraVent-5 Ventilator is a self-contained, portable ventilator, consisting totally of non-magnetic components which include: (10 a gas inlet connector, (2) a gas inlet filter, (3) two timing valves, (4) a pilot actuator valve, (5) a flow metering valve, and, (6) a pressure-relief valve. During the inspiratory time phase of the system, a small portion of the gas flowing through the system is diverted to the exhalation valve diaphragm, inflating the diaphragm in sequence with the inspiratory time, thereby allowing the main gas flow from the Device to flow to the patient. During the expiratory phase, all ventilator gas flow ceases, the exhalation valve opens and the patients's exhaled gases flow to atmosphere. These characteristics are illustrated in the Operators and Service Manual, Attachment 1.

Performance Data Verification of Device and Identical Predicate Device

Performance testing was conducted that confirms that the device operates as designed. In all instances, the EnduraVent-5 Ventilator functioned as intended and delivery of the gas volumes, frequencies, and safety devices was verified. Bench testing with the Endura-Vent-5 and the predicate Magellan Ventilator was made to verify the production process of the EnduraVent-5 using the exactly the same protocols used by both factories

Substantial Equivalence

The EnduraVent-5 Ventilator is as safe and effective as the predicate Magellan Ventilator. The EnduraVent-5 Ventilator has the same intended uses, exactly duplicated technological characteristics and components, and exactly the same principles of operations as its predicate device. Any minor labeling differences between the EnduraVent-5 Ventilator and its predicate device raise no new issues of safety or effectiveness. Thus, the EnduraVent-5 Ventilator is substantially equivalent.

The same person that developed the predicate (K002951) Magellan Ventilator, has now replicated the predicate device with the EnduraVent-5 Ventilator. The predicate device has been in continuous production since 2000 with zero reported problems to either the FDA or the Manufacturer during that time.

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

Ms. Helen Redd
President
Providence Global Medical, Incorporated
4659 South 2300 East, 203
Salt Lake City, Utah 84117

JAN 21 2010

Re: K092263
Trade/Device Name: EnduraVent-5 Ventilator
Regulation Number: 21CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 14, 2010
Received: January 14, 2010

Dear Ms. Redd:

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,

for

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 Statement

510(k) Number (if known) K092263

Device Name: EnduraVent-5 Ventilator

Indications for Use:

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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

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

510(k) Number: K092263