510(K) SUMMARY

K083688

MAR 18 2009

SUBMITTER

Cardinal Health 203, Inc.
17400 Medina Road, Suite 100
Minneapolis, Minnesota 55447-1341

Contact Person: Robert C. Samec
(763) 398-8305 Telephone
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DEVICE / TRADE NAME

Trade Name: LTV 1200 MR Conditional Ventilator

Common Name: Ventilator

Classification Name: Ventilator, Continuous (Respirator) 868.5895

SUBMISSION DATE

Submission Date: December 11, 2008

DESCRIPTION

The LTV 1200 ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is suitable for use in institutional, home and transport settings, and is applicable for adult and pediatric patients weighing at least 5 kg (11 lbs.), who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control, SIMV, CPAP, or NPPV modes of ventilation.
- Breath types including Volume, Pressure Control and Pressure Support.

The modification intended to be cleared by this submission is:

The "Indications for Use" is being expanded to label the LTV 1200 as MR Conditional.

The LTV 1200 Ventilator, previously cleared for homecare, institutional and transport use is now being submitted for clearance with the listed modification.

INTENDED USE

The LTV® 1200 ventilator is intended to provide continuous or intermittent ventilatory support for the care of the 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 weighing at least 5kg (11 lbs.), who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via endotrach tube or trach tube) or non-invasively (via mask or nasal prongs).
- Assist/Control, SIMV, CPAP, or NPPV modes of ventilation.

The ventilator is suitable for use in institutional, home, or transport settings.
The MR Conditional LTV® 1200 System is suitable for use in both 1.5 and 3.0 Tesla (not to exceed 3.0 Tesla static magnetic field) shielded magnetic scanners.
CAUTION: Federal law restricts this device to sale by or on the order of a physician

EQUIVALENCE TO PREDICATE DEVICE(S)

Testing conducted in the MR environment has demonstrated that the LTV 1200 MR Conditional ventilator is substantially equivalent to the predicate device listed below.

The LTV 1200 with the modification listed is substantially equivalent to the predicate device(s) listed.

Predicate Device	510(k) Clearance	Manufacturer
iVent 201 MR Conditional Portable Ventilator	**K073694**	**Versamed Corporation 2 Blue Hill Plaza Pearl River, NY 10965**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2009

Mr. Robert C. Samec
Vice President, QRA
Cardinal Health 203, Incorporated
17400 Medina Road
Suite 100
Minneapolis, Minnesota 55447

Re: K083688
Trade/Device Name: Ventilator, Continuous (Respirator)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 11, 2008
Received: December 22, 2008

Dear Mr. Samec:

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,

Ginette Y. Michaud, M.D.
Acting 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) K083688

Device Name *Ventilator, Continuous (Respirator)*

Indications for Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801. 109)

Susan Runner

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

510(k) Number: K083688