CareFusion

K101643

510 (K) Summary as required by 21 CFR 807.92

510 (K) Submitter:

CareFusion
Yorba Linda, CA 92887
(714) 283 – 2228

JAN 26 2011

Contact Person:

Monther Abushaban
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Establishment Registration Number: 2050001

Date Prepared: January 11,2011

Name of the Device: LTV 1100 Ventilator

Common/ usual name: ventilator

Classification: The LTV 1100 ventilator is classified as a class II device under the following classification code

Product code	CFR Section	Panel
73 CBK	21 CFR 868.5895	Anesthesiology

Predicate Device: LTV 1200 ventilator (K060647), Vela (K093094), LTV800 (K981371)

Device Description: The LTV® 1100 ventilator is designed to provide the functionality in a small package. The LTV® 1100 ventilator provides the following features:

- ventilator is (10.5" x 13.5" x 3.25", 14.5 lbs).
- Turbine technology allows the ventilator to operate without an external compressed gas source.
- $CPAP_2$, $SIMV_3$, Control, Assist/Control and Apnea Backup ventilation modes.
- $NPPV_4$ mode ventilation, providing an alarm package suitable for mask ventilation of patients that do not require life support ventilation.
- Volume Control and Pressure Support ventilation.
- Spontaneous Breathing Trial (SBT) to assist with weaning and discontinuation of ventilatory support.
- Variable alarm settings including High Peak Pressure, Low Peak Pressure, Low Minute Volume, Apnea, High Breath Rate, High PEEP and Low PEEP.
- Low-Pressure Oxygen Bleed-in
- Lockable front panel controls.
- Monitors for Breath Rate (f), I:E Ratio, MAP, Minute Ventilation (VE), PEEP, PIP and Tidal Volume (Vte).
- Real-time patient circuit pressure display with Peak Inspiratory Pressure indicator.
- Variable termination conditions for Pressure Support breaths, including maximum inspiratory time termination and percentage of peak flow.
- Leak Compensation to improve triggering when a circuit leak is present.

- Single or dual tone output capabilities.
- Operation from a variety of power sources including AC power, internal battery and external DC power sources.
- Flow Sensor and No Flow Sensor configuration modes allow for a flow sensing patient circuit or a non-flow sensing patient circuit to be used.

Intended Use: The LTV® 1100 ventilator is intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. The ventilator is a 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, and NPPV modes of ventilation.

The ventilator is suitable for use in institutional, home, or transport settings.

Substantial Equivalence: The LTV 1100 ventilator is the same device as the predicate device LTV 1200, LTV800 and Vela ventilator. Modifications to the software by adding more features did not affect the intended use. The modifications to the software associated with this submittal are as follows:

- Translations for LEAK COMP On & OFF
- Sigh
- Patient Circuit Selection

In summary, the LTV 1100 ventilator described in this submission is, in our opinion substantially equivalent to the predicate device.

Summary of Testing and Validation: Performance testing verified that the LTV 1100 ventilator meets it's performance requirements that this device is substantially equivalent to medical devices currently legally marketed in the United States.

Reason for the submission: This Traditional 510 (k) Premarket Notification is a submission for minor software and hardware changes to a current device, LTV 1200 510(k) No. K060647. These changes are features that have been added such as Sigh Breaths, Patient Circuit Mode and Adjustable rate in NIV.

The modified device also includes minor changes of appearance, operator controls and displays. There are no changes to the fundamental technology as compared to the predicate device.

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

Mr. Monther Abushaban
Regulatory Affairs Manager
Carefusion
22745 Savi Ranch Parkway
Yorba Linda, California 92887

JAN 26 2011

Re: K101643
Trade/Device Name: Model LTV 1100 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 9, 2010
Received: January 6, 2011

Dear Mr. Abushaban:

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

CareFusion

510 (K) Number (if Known): K101643
Device Name: LTV 1100 Ventilator

Indications for Use

Device Name: LTV 1100

Indications for Use:

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The ventilator is suitable for use in institutional, home, or transport settings.

Prescription Use____X____ AND/ OR Over the Counter Use:_____
(Part 21CFR 801 subpart D) (Part 21CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

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