K103318

IMPACT Instrumentation Inc.

APR - 7 2011

27 Fairfield Place, West Caldwell, NJ 07006.
P.O Box 508, West Caldwell, NJ 07007-0508

510(k) Summary

This 510(k) summary consists of a table with the information required in the 510(k) Summary Checklist from the FDA Guidance document. It also includes the completed checklist with approval signature.

Description of Required Information	Information
Owner's Name	Leslie H. Sherman (President)
Address	27 Fairfield Place, West Caldwell NJ 07006
Phone	973-882-1212
Fax	973-882-4993
Contact Person	Susan McNevin Ph.D., CQA/ CQE Quality Engineer
Date this Summary was prepared	January 4, 2011
Trade name of device	Uni-Vent® 731 Series Model EMV+® Portable Critical Care Ventilator
Common name	ventilator
Classification name	Continuous Ventilator (21 CFR 868.5895, Product Codes CBK, DQA)
Legally marketed device – Equivalence Claim	This device has updated software from the Predicate EMV+ ventilator (K091238). This update provides SIMV (Synchronized Intermittent Mandatory Ventilation) and CPAP (Continuous Positive Airway Pressure) modes with ventilator support options of Pressure Support and Leak Compensation.

<table>
<tr><th>Description of Required Information</th><th>Information</th></tr>
<tr><td>Description of the device</td><td>

MODES OF OPERATION

The EMV+ offers a range of modes using both pressure and volume targeting that can be selected to optimally manage the patient.

Assist/Control (AC): patient receives either controlled or assisted breaths. When the patient triggers an assisted breath they receive a breath based on either the volume or pressure target.

Synchronized Intermittent Mandatory Ventilation (SIMV): patient receives controlled breaths based on the set breathing rate. Spontaneous breaths can be either unsupported or supported using Pressure Support. (The software implementation allows for devices to be configured with and without the SIMV mode feature.)

Continuous Positive Airway Pressure (CPAP): patient receives constant positive airway pressure while breathing spontaneously. Spontaneous breaths can be either demand flow or supported using Pressure Support.

ADDITIONAL ADJUNCTS OF OPERATION

In addition to Modes of Operation, the EMV+ also provides various adjuncts that can be used to manage the patient. Two adjuncts are Pressure Support (PS) and Noninvasive Positive Pressure (NPPV). The table below shows which adjuncts can be used with which modes. It is possible to use more than one adjunct, if the mode permits.

Mode	Breath Target	Pressure Support (PS)	Noninvasive Positive Pressure Ventilation (NPPV)
AC	V & P	No	No
SIMV	V & P	Yes	No
CPAP	N/A	Yes	Yes

Pressure Support (PS): can be used to assist spontaneous breaths in both SIMV and CPAP modes.

Noninvasive Positive Pressure (NPPV): provides flow during the expiratory phase to maintain the baseline pressure (CPAP) in spontaneously breathing patients with a leaking airway or facemask. The amount of leak compensation depends on the leak flow rate during the expiratory period and ranges from 0 to 15 liters/min and is automatically adjusted by the ventilator in order to maintain the CPAP target.

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<table>
<tr><th>Description of Required Information</th><th>Information</th></tr>
<tr><td>Intended Use of Device</td><td>The Intended Use is the same as the Predicate device (K091238):
"The Model 731EMV+ (EMV+) is indicated for use in the management of infant through adult patients weighing ≥5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. It is appropriate for use in hospitals, outside the hospital, during transport and in austere environments where it may be exposed to rain, dust, rough handling and extremes in temperature and humidity. With an appropriate third-party filter in place, it may be operated in environments where chemical and/or biological toxins are present (see External Filter Use). It is <u>not</u> intended to operate in explosive environments. The EMV+ is intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation and by first responders under the direction of skilled medical care providers. "</td></tr>
<tr><td>Comparison Technological Characteristics to Predicate</td><td>The changes modify the specification of the device in the following manner:
<table>
<tr><th>EMV+ (K091238)</th><th>Modified EMV+</th></tr>
<tr><td>Operating Mode: AC</td><td>Operating Mode: AC, SIMV, CPAP with and without Pressure support and with and without Noninvasive Positive Pressure Ventilation (NPPV)</td></tr>
<tr><td>PEEP: 0 to 25 cm H2O</td><td>PEEP: 0 to 25 cm H2O (The minimum PEEP in CPAP-NPPV is 3 cm H20)</td></tr>
</table>
• There is no change to the product materials or biocompatibility.
• There is no change to the power input or battery usage.
• There is no change to Impact®'s intended use statement.
• There is no change to the devices' fundamental scientific technology.
The operating principals remain the same. The modified EMV+ provides the operator methods consistent with the standard of care for managing patients with acute or chronic respiratory failure.</td></tr>
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<tr><th>Description of Required Information</th><th>Information</th></tr>
<tr><td>Non-Clinical Performance data</td><td>This device meets the same performance criteria as the Predicate (K091238). These criteria are specified by:
<table>
<tr><th>Standard</th><th>Standard Title</th></tr>
<tr><td>ASTM F1100-90</td><td>Ventilators Intended for use in Critical Care</td></tr>
<tr><td>IEC 60601-1</td><td>Medical Electrical Equipment – Part 1, General Requirements for Safety</td></tr>
<tr><td>ISO 9919:2005</td><td>Medical electrical equipment- particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use</td></tr>
</table>
Additional Environmental Standards:
<table>
<tr><td>Mil-Std-461F</td><td>Requirements for the Control of Electromagnetic Interference Characteristics of Subsystems and Equipment</td></tr>
<tr><td>Mil-Std-810F</td><td>Environmental Engineering Considerations and Laboratory Tests</td></tr>
</table></td></tr>
<tr><td>Clinical Performance</td><td>N/A. No clinical performance data is being submitted.</td></tr>
<tr><td>Safe and Effective as Predicate</td><td>The device design and development process is the same as the Predicate (K091238). It was in accordance with:
<table>
<tr><td>ISO 13485</td><td>Quality Systems – Medical Devices</td></tr>
<tr><td>ISO 14971</td><td>Medical Devices – Application of Risk Management to Medical Devices</td></tr>
</table>
The resulting device being submitted is as safe and effective as the Predicate (K091238).</td></tr>
<tr><td>Other Information requested by FDA</td><td>Impact Instrumentation, Inc. will provide the FDA with any additional required information.</td></tr>
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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

Susan McNevin, Ph.D
Quality Engineer
Impact Instrumentation, Incorporated
27 Fairfield Place
West Caldwell, New Jersey 07006

APR - 7 2011

Re: K103318
Trade/Device Name: Uni-Vent®) 731 Series Model EMV+® Portable Critical Care Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK and DQA
Dated: March 30, 2011
Received: March 31, 2011

Dear Dr. McNevin:

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.

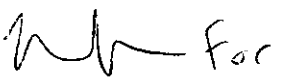
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony 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

510(k) Number (if known):

Device Name: Uni-Vent®) 731 Series Model EMV+® Portable Critical Care Ventilator

Indications For Use:

The Model 731EMV+ (EMV+) is indicated for use in the management of infant through adult patients weighing ≥5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. It is appropriate for use in hospitals, outside the hospital, during transport and in austere environments where it may be exposed to rain, dust, rough handling and extremes in temperature and humidity. With an appropriate third-party filter in place, it may be operated in environments where chemical and/or biological toxins are present (see External Filter Use). It is not intended to operate in explosive environments. The EMV+ is intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation and by first responders under the direction of skilled medical care providers.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103318