K091238

IMPACT Instrumentation, Inc.

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

AUG 1 8 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Impact, Uni-Vent® Model 731EMV+
510(k) Number -

Manufacturer:	Impact Instrumentation, Inc. P.O. Box 508/27 Fairfield Place West Caldwell, New Jersey 07006 Phone: 973-882-1212 Fax: 973-882-4993
Contact Person:	Mr. Leslie H. Sherman
Date Summary Prepared:	April 23, 2009
Trade Name:	Uni-Vent ® Model 731EMV+
Classification Name:	Continuous Ventilator (per 21 CFR 868.5895)
Classification:	Class II
Product Code:	CBK, DQA

Device Description:

The Uni-Vent ® Model 731EMV+ is a portable, microprocessor controlled, electrically or pneumatically powered intensive care ventilator designed to use either oxygen (O_2) from a 55 psig source or ambient air using an internal compressor power to deliver a positive pressure breaths. The unit can be electrically powered from an external alternating current source, external direct current (DC) source or the internal DC battery. An intuitive point-turn-and click interface allows the operator to set and monitor ventilation in all operating environments. A series of alarms alert the user operator to all conditions that affect the ventilator's operation and/or performance and provide context sensitive help relevant to the alarm condition. Ambient air is filtered using a particulate filter or when the operating environment requires either a bacterial/viral or chemical/biologic (NATO No: 4240-01-361-1319) filter. The unit is contained in an impact resistant polycarbonate case which protects of the controls from damage and inadvertent manipulation.

Description of Noninvasive Pulse Oximeter
The Uni-Vent ® Model 731EMV+ internal pulse oximeter connects to the patient using noninvasive sensors to monitor oxygen saturation and pulse rate. Pulse oximeter specific alarms and instructions are presented to the operator through the user interface. Isolated DC power is provided to the pulse oximeter.

Intended 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.

Substantial Equivalence: The Impact, Model 731EMV+, is substantially equivalent to the predicate devices listed below:

Predicate Devices:

1. Impact, Model 731EMV.
   510(k) # K071526
2. Pulmonetic Systems, Inc. LTV 1200 Ventilator.
   510(k) #K060647

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Leslie H. Sherman
President
IMPACT Instrumentation, Incorporated
27 Fairfield Place
West Caldwell, New Jersey 07006

AUG 18 2009

Re: K091238
Trade/Device Name: Uni-Vent ® Model 731 EMV+
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, DQA
Dated: July 10, 2009
Received: July 14, 2009

Dear Mr. Sherman:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division 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 ® Model 731EMV+

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 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, Dental Devices

510(k) Number: K091236