MAR 2 6 2004

IMPACT Instrumentation, Inc.

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

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Impact, Uni-Vent® AEV™ Model 730
510(k) Number K032386

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:	July 25, 2003
Trade Name:	Uni-Vent ® Model 730AEV™
Classification Name:	Powered Emergency Ventilator (21 CFR Sec. 868.5925)
Classification:	Class II
Product Code:	BTL
Predicate Devices:	1. Impact Models 701, 702, 703. 510(k) #K861272/A. 2. Uni-Vent- MinuteVolume Ventilator, Model 750. 510(k) #K870861/B. 3. Uni-Vent- Eagle, Model 754. 510(k) #K870861/B and K931473. 4. Smartvent 201 (CBK) Portable Ventilator. 510(k) #K981668

Performance Standards:	The Model 730 AEV™ complies with the following voluntary standards ASTM F920-99, ASTM F1100-97, ISO9703-1, ISO 9703-2, CGA V-5:2000, ISO 5356-1, EN1441, MIL-STD-1472F, ANSI/AAMI HE74:2001, MIL- STD-810F, EN60601-1. No applicable mandatory performance standards or special controls exist for this device.
Performance Guidelines:	International Guidelines 2000 for CPR and ECC. Standard-of-Care Ventilator Settings - originally described by Radford (N. Engl. J. Med. 251:877-883, 1954). Reviewer Guidance for Premarket Notification Submissions Nov 1993. Reviewers Guidance for Ventilators July, 1995.
Device Description:	Model 730 AEV™ is a portable, electronically controlled ventilator. It is controlled by an internal microprocessor (CPU), which continuously monitors and displays airway pressure, control settings, high-pressure alarm setpoint, gas volumes, and power signals. Two CPR and two Quick-Start Modes are available- one each is for use with unintubated patients (Mask) and one each is for use with intubated patients (Tube). This product operates from internal rechargeable batteries, external AC and 11-15 volts DC.
Intended Use:	The Model 730 AEV™ is intended to provide continuous ventilatory support for individuals during CPR or when positive-pressure ventilation is required to manage acute respiratory failure. It is appropriate for use with adults and children – in clinical, field hospital, transport, aeromedical and pre-hospital (BLS through ATLS) environments.
Substantial Equivalence:	The Impact, Model 730 AEV™, is substantially equivalent to the Impact Instrumentation Inc. Models 701, 750, 754 and the Versamed Smartvent 201 in that: - the intended use is the same - the principle performance attributes are the same Based on safety and performance testing including a comparative examination and analysis of similarities and differences to its predicate devices no new safety and/or effectiveness issues have been raised.

Impact Instrumentation, Inc. - P.O. Box 508 - West Caldwell, NJ 07007-0508 Tel: 973.882.1212 Fax: 973.882-4993

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Leslie H. Sherman
President
Impact Instrumentation, Incorporated
27 Fairfield Place
PO Box 508
West Caldwell, New Jersey 07006

Re: K032386
Trade/Device Name: Uni-Vent Model 730AEV
Regulation Number: 21 CFR 868.5925
Regulation Name: Emergency Powered Ventilator (Resuscitator)
Regulatory Class: II
Product Code: BTL
Dated: not dated
Received: February 25, 2004

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 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.

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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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IMPACT Instrumentation, Inc.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032386

Device Name: Uni-Vent ® Model 730AEV™ (Automatic Emergency Ventilator)

Indications for use:

The Model 730 AEV ™ is intended to provide continuous ventilatory support for individuals during CPR or when positive-pressure ventilation is required to manage acute respiratory failure. It is appropriate for use with adults and children- in clinical, field hospital, transport, aeromedical and pre-hospital (BLS through ATLS) environments.

Prescription Use _XXX_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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: K032386

Tel: 973.882.1212 Fax: 973.882.4993
Web Site & E-Mail: http://www.impactinstrumentation.com