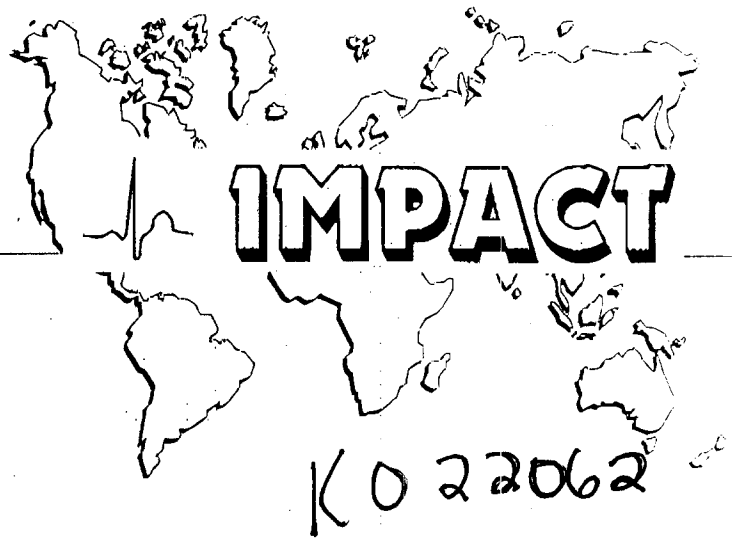
IMPACT Instrumentation, Inc.

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



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K022062

SMDA REQUIREMENTS – ABBREVIATED 510(k)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Impact, Universal Single-Limb, Portable Ventilator Circuit

Manufacturer:	Impact Instrumentation, Inc. P.O. Box 508 27 Fairfield Place West Caldwell, New Jersey 07006
Regulatory Affairs Contact:	Mr. Leslie H. Sherman P.O. Box 508 27 Fairfield Place West Caldwell, New Jersey 07006
Telephone:	973.882.1212
Facsimile:	973.882.4993
Date Summary Prepared:	March 4, 2003 (Amended from June 20, 2002)
Trade Name:	Impact, Universal Single-Limb, Portable Ventilator Circuit
Common Name:	Ventilator circuit
Classification Name:	Accessory to Continuous Ventilator per 21 CFR 868.5895
Product Code:	MOD
Classification:	Class II
Predicate Device:	Allegiance Healthcare Corporation, Catalog Number 1755 (K801875), Airlife™ Universal Portable Volume Ventilator Circuit (Dual Limb).

Description:	The Impact, Universal Single-Limb, Portable Ventilator Circuit is comprised of disposable connectors, tubing and exhalation valve. It is intended for use with adults and medium-to-large pediatric patients.
Intended Use:	Impact Universal Single-Limb Ventilator Circuit is intended for use in conjunction with ventilators Having a single-limb circuit interface. The ventilator circuits are used as a means by which to transfer breathing gases from a ventilator to a patient (inhalation) and from a patient to atmosphere (exhalation). The device is intended for use with adults and medium to large pediatric patients.
Substantial Equivalence:	The Impact, Universal Single-Limb, Portable Ventilator Circuit is substantially equivalent to the Allegiance Healthcare Corporation, Catalog Number 1175, Airlife™ Universal Portable Volume Ventilator Circuit in that: - the intended use is the same - the performance attributes are the same
Summary of Testing:	Materials used in the fabrication of the Impact, Universal Single-Limb, Portable Ventilator Circuit were evaluated through biological qualification safety tests as outlined in: ISO 10993 Part 1 "Biological Evaluation of Medical Devices", ISO 10993 Part 5 "Tests for in vitro cytotoxicity", ISO 10993 Part 12 "Sample Preparation and Reference Materials", USP 25 "Biological Reactivity Tests, in vivo - Classification of Plastics", and 21 CFR 177.1350 "Ethylene-Vinyl Acetate Copolymers" In addition, the Impact, Universal Single-Limb, Portable Ventilator Circuit was tested in accordance with industry recognized test methods contained in ASTM F-1100, Table 2, and was found to be acceptable for its intended use.

Proposed Labeling

Previously supplied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

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

Re: K022062
Trade/Device Name: Impact, Universal Single-Limb, Ventilator Circuit
Regulation Number: 868.5895
Regulation Name: Accessory to Continuous Ventilator
Regulatory Class: II
Product Code: MOD
Dated: February 6, 2003
Received: February 7, 2003

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. 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022062

Statement of Indications for Use

Impact Universal Single-Limb Ventilator Circuit is intended for use in conjunction with ventilators having a single-limb circuit interface. The ventilator circuits are used as a means by which to transfer breathing gases from a ventilator to a patient (inhalation) and from a patient to atmosphere (exhalation). The device is intended for use with adults and medium to large pediatric patients.

Prescription Use Only ✓

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

510(k) Number: K022062