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MEDIC-AID

Non-Confidential Summary of Safety and Effectiveness

May 27, 1997

AUG - 1 1997

Medic-Aid Ltd.
Heath Place
Bognor Regis, West Sussex PO22 9SL
United Kingdom

Tel - 011-44-1243-840888 Fax - 011-44-1243-846100

Official Contact:	Ed Walters, Quality Manager
Proprietary or Trade Name:	Medic-Aid - Porta-Neb Nebulizer Compressor
Common/Usual Name:	Nebulizer compressor
Classification Name:	Non-ventilatory, medicinal nebulizer (atomizer)
Device:	Medic-Aid Porta-Neb
Predicate Devices:	DeVilbiss - Pulmo-Aide K85520

Device Description:

The Medic-Aid Porta-Neb is an electrically powered compressor which provides 6-8 Lpm of air flow under a back pressure of 12 psi. It is designed to be connected to a hand-held nebulizer to provide the air source to nebulize drugs to be inhaled by a patient.

Indicated Use --	To provide a portable compressed air source for the nebulization of drugs to be delivered to a patient via a hand-held nebulizer.
Environment of Use --	Hospitals, nursing home and homes.
Patient population --	Patients requiring nebulized drug delivery.

Comparison to Predicate Devices:

Attribute	Porta-Neb	DeVilbiss Pulmo-Aide K854520
Use		
Intended to nebulize drugs	Yes	Yes
Utilized with different nebulizers	Yes	Yes
Serves as a air source to drive nebulizers	Yes	Yes
Portable	Yes	Yes
Used in hospital, nursing home, or home	Yes	Yes
Design		
Small, compact, portable	Yes	Yes
Operates on 110 Volt	Yes	Yes
Nebulizer flow rates -	6-8 Lpm	5-7 Lpm
Has air outlet to connect to air delivery tubing which connects to nebulizer	Yes	Yes
Is used with nebulizer, mask or mouthpiece	Yes	Yes
Materials		
No materials related to this device are in contact with the patient	Yes	Yes
Packaging		
Provided clean	Yes	Yes
Performance Standards / Specifications		
None applicable under Section 514	Yes	Yes

Attribute	Porta-Neb	DeVilbiss Pulmo-Aide K854520
Meets design, safety and performance requirements of EN 60601, UL 2601, IEC 601-1, CAN / CSA C22.2 No.60 1.1	Yes	Not known, but assumed Yes

Differences between Other Legally Marketed Predicate Devices

There is no differences between the intended device and the predicate devices which would be significant to patient safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Ed Walters
Medic-Aid, Ltd.
c/o ProMedic, Inc.
6329 W. Waterview Court
McCordsville, Indiana 46055-4501

AUG - 1 1997

Re: K971933
Porta-Neb Nebulizer Compressor
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: May 27, 1997
Received: May 27, 1997

Dear Mr. Walters:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K971933 (To be assigned)

Device Name: Medic-Aid, Ltd. Porta-Neb, nebulizer compressor system

Intended Use : To provide a portable compressed air source for the nebulization of drugs to be delivered to a patient via a hand-held nebulizer in the home, nursing home or hospital environments.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____