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NOV 3 1998 K981772

MEDIC-AID

Non-Confidential Summary of Safety and Effectiveness

May 18, 1998

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:	HaloLite ™ AAD
Common/Usual Name:	Nebulizer
Classification Name:	Nebulizer, Direct Patient Interface
Predicate Devices:	Vortran - AutoNeb K935693
	Medic-Aid - Ventstream - K933535

Device Description:

The Medic-Aid HaloLite AAD system is a single patient use, prescribed portable nebulizer designed to deliver a precise and reproducible dose of aerosolized liquid medication. The device consists of a hand-piece containing a pressure transducer, a microprocessor control system, and a medication chamber, based on the Medic-Aid - Ventstream Nebulizer, K933535, and mouthpiece.

The HaloLite system analyses the patient's breathing pattern to determine the aerosol pulse time. The system then pulses aerosol during inspiration only. Each pulse of aerosol is matched according to the inspiratory time. HaloLite continues to monitor the breathing pattern in order to adapt to changes in breathing throughout the treatment. When the pre-set dose has been delivered, the system indicates that the treatment is complete.

1. Intended use - Aerosolization of commonly prescribed liquid drug (except Pentamidine) for inhalation by the patient.

2. Environment of Use - Single patient / multi-use for Home, Hospitals and Nursing Homes

3. Patient Population - Patients requiring nebulized drug delivery via a mouthpiece.

Comparison to Other Legally Marketed Predicate Devices

The following comparison table details the primary attributes of the intended device and legally marketed predicate devices. The most significant attributes have been listed.

Attribute	HaloLite AAD System	Medic-Aid Ventstream K933535	Vortran AutoNeb K935693
Use			
Intended to nebulize drugs	Yes	Yes	Yes
Sidestream Jet System	Yes	Yes	No
Synchronized Delivery of Nebulized drug	Yes	No	Yes
Drug Delivery on demand	Yes	No	Yes
Used in hospitals, home care, nursing home settings	Yes	Yes	Yes
Single Patient / Multi-use	Yes	Yes	N/A
Design			
Flow Rates	6 LPM	6-8 LPM	1.5-16LPM
Gas Source - Compressed Air	Yes	Yes	Yes
Software Driven	Microprocessor	No	No
Mode of Operation	Turn on During Patient Inhalation	Breath Enhanced Continuous System	Turn on During Patient Inhalation

Attribute	HaloLite AAD System	Medic-Aid Ventstream K933535	Vortran AutoNeb K935693
Drug delivery triggered by	Patient Inhalation Airway Pressure Signal	None	Patient Inhalation Airway Pressure Signal
Used with Mouthpiece	Yes	Yes	Yes
Materials			
Materials in Contact with Patient Polypropylene	Mouthpiece	Mouthpiece	Mouthpiece
Packaging			
Provided clean, non-sterile	Yes	Yes	Yes
Performance Standards / Specifications			
None applicable under Section 514	Yes	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices

The differences between the intended device, HaloLite, and the predicates are -

1. The HaloLite system provides a hand-held, user-friendly device compared with the bench-mounted Vortran - AutoNeb which requires tubes to interconnect between the AutoNeb and a standard nebulizer.

2. The HaloLite is micro-processor controlled device. This permits the HaloLite device to operate across a wide range of patient ages and breathing patterns, without requiring any calibration or adjustment to sensitivity settings as required by the AutoNeb. The system can also adapt to any changes in the breathing pattern and adjust to the aerosol pulse time throughout the treatment. Each aerosol pulse is

summed to provide an accurate method of dose measurement so that a pre-set dose can be delivered. The HaloLite operates over a pulse range of 0.15 to 2.0 seconds compared to the Vortran AutoNeb 0.5 to 5.0 seconds. This range has been selected as being the most appropriate to match the patient's inhalation.

3. The Vortran AutoNeb can also be used to deliver a pre-set dose. This requires setting the controls for each patient's breathing pattern, and counting the number of pulses delivered to the patient. This is achieved automatically with the HaloLite, the press of a button initiates treatment and when the pre-set dose has been delivered the device signals that the treatment has been completed. This system provides ease of use for both the physician and the patient. The Vortran - AutoNeb is operated from 115 volt mains supply, and the HaloLite is powered by an internal replaceable 9 volt battery.

There is no other 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 20850

NOV 3 1998

Mr. Paul E. Dryden
Medic-Aid, Ltd.
c/o ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055-9501

Re: K981772
HaloLite AAD System
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: September 8, 1998
Received: September 9, 1998

Dear Mr. Dryden:

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 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). 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/dsma/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

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: K981772 (To be assigned)

Device Name: HaloLite AAD System

Intended Use : A Nebulizer system designed to aerosolize commonly prescribed liquid medication (except Pentamidine) for inhalation by the patient in the home care, nursing home or hospital environment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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