

AUG 13 1999

Medic-Aid Limited
Heath Place, Bognor Regis, West Sussex, UK PO22 9SL
Telephone (01243) 840888 Fax (01243) 846100

K991685



Non-Confidential Summary of Safety and Effectiveness

page 1 of 3

May 14, 1999

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 with Dedicated Compressor System
Common/Usual Name: Nebulizer
Classification Name: Nebulizer, Direct Patient Interface
Predicate Devices: Medic-Aid HaloLite ADD System - K981772
Invacare - Medi-Pump Mobilaire (50 psi Compressor)
K950867

Device Description:

The Medic-Aid HaloLite AAD system with dedicated compressor 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, a medication chamber, and dedicated compressor to provide a compressed air source. Other compressed air sources can be - Invacare Mobilaire (50 psi compressor) and regulate wall compressed air.

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.



Non-Confidential Summary of Safety and Effectiveness

page 2 of 3

May 14, 1999

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 Compressor System	HaloLite AAD System K981772 + Wall supply driving gas	HaloLite AAD System K981772 + Medi-Pump K950867
-----------	--------------------------------	---	---

Use

Intended to nebulize drugs	Yes	Yes	Yes
Synchronized Delivery of Nebulized drug	Yes	Yes	Yes
Drug Delivery on demand	Yes	Yes	Yes
Used in hospitals, home care, nursing home settings	Yes	Yes	Yes
Single Patient / Multi-use	Yes	Yes	Yes

Design

Dynamic Pressure at Nebulizer Jet	1.75 bar	1.75 bar	1.75 bar
Gas Source - Compressed Air	Yes	Yes	Yes
Software Driven	Microprocessor	Microprocessor	Microprocessor

Non-Confidential Summary of Safety and Effectiveness

page 3 of 3

May 14, 1999

Attribute	HaloLite AAD Compressor System	HaloLite AAD System K981772 + Wall supply driving gas	HaloLite AAD System K981772 + Medi-Pump K950867
------------------	---------------------------------------	--	--

Design

Drug delivery triggered by	Patient Inhalation Airway Pressure Signal	Patient Inhalation Airway Pressure Signal	Patient Inhalation Airway Pressure Signal
Used with Mouthpiece	Yes	Yes	Yes

Materials

No significant changes

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

There are no differences in performance, safety, or efficacy between the new dedicated compressor and the Invacare compressor or regulated wall gas.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

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

Re: K991685
HaloLite ADD System with Compressor
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: May 14, 1999
Received: May 17, 1999

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.

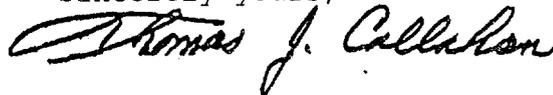
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Paul E. Dryden

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, 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.

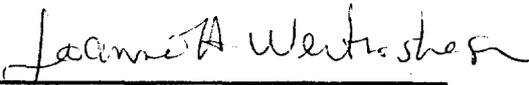
510(k) Number: K991685 (To be assigned)

Device Name: HaloLite AAD System with Compressor (modification)

Intended Use : A HaloLite Adaptive Aerosol Delivery, (AAD) system, a handheld nebulizer system including a dedicated compressor is designed to aerosolize commonly prescribed liquid medication (except Pentamidine) for inhalation by the patient in the home care, nursing home or hospital environment.

The new dedicated compressor provides a compressed air source similar to the original predicate device compressed air sources, Invacare Mobilaire and regulated wall air.

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)