JUL 30 1999

K991725

Inspired Medical Products, Ltd.
Heath Place
Bognor Regis, West Sussex PO22 9SL
United Kingdom

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

Non-Confidential Summary of Safety and Effectiveness

May 19, 1999

Inspired Medical Products, 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:	Sidestream Drug Nebulizer
Common/Usual Name:	Nebulizer
Classification Name:	Nebulizer, Medicinal, Non-ventilatory (atomizer)
Predicate Devices:	Medic-Aid - Sidestream Nebulizer - K924123
	Medic-Aid - Sidestream Nebulizer - K914152B

Device Description:

The Inspired Medical Products Sidestream Nebulizer is identical to the Medic-Aid Sidestream Nebulizer cleared under K924123.

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

2. Environment of Use - Single patient use for the Home, Hospital and Nursing Home settings - anywhere aerosolized drug delivery is utilized.

3. Patient Population - Patients requiring nebulized drug delivery.

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	Inspired Med. Sidestream Nebulizer disposable	Medic-Aid Sidestream Nebulizer disposable K924123	Medic-Aid Sidestream nebulizer K914152B
Use			
Intended to nebulize drugs	Yes	Yes	Yes
Utilizes Sidestream jet system to nebulize drug	Yes	Yes	Yes
Used in hospitals, home care, nursing home settings - anywhere aerosolized drug delivery is utilized	Yes	Yes	Yes
Single Patient Use	Yes	Yes	Yes
Design			
Utilizes same technology to atomize drugs	Yes	Yes	Yes
Gas Source - Compressed Air	Yes	Yes	Yes
Made of three components - top, baffle, base	Yes	Yes	Yes
Used with Mouthpiece	Yes	Yes	Yes

Attribute	Inspired Med. Sidestream Nebulizer disposable	Medic-Aid Sidestream Nebulizer disposable K924123	Medic-Aid Sidestream nebulizer K914152B
Materials			
Materials in contact with patient - polypropylene	Yes	Yes	Yes
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 intended device and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Mr. Paul Dryden
Inspired Medical Product, Ltd.
c/o ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055-9501

Re: K991725
Sidestream Drug Nebulizer
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: May 19, 1999
Received: May 20, 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 (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, 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: K991725 (To be assigned)

Device Name: Sidestream nebulizer

Intended Use : A hand-held nebulizer to aerosolize commonly prescribed liquid drugs (except pentamadine) for inhalation by patients in the Home, Hospital and Nursing Home settings - anywhere aerosolized drug delivery is utilized.

Concurrence of CDRH, Office of Device Evaluation (ODE)

J A Weitzhandler 7/30/99

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991725

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