510(k) SUMMARY
for
Neb-90™ Large Volume Medication Nebulizer

JUN 30 2008

1. SUBMITTER INFORMATION:

Medi/Nuclear Corporation, Inc.
4610 Littlejohn Street
Baldwin Park, CA 91706-2267

Establishment
Registration Number: 2050098

Primary contact: **Jerry Schoen**
Chief Operating Officer
Medi/Nuclear & Healthline Medical
Telephone Number: **(800) 321-5981 (corporate toll-free)**
(626) 960-9822 (Los Angeles local)
Fax: **(626) 960-8700 (corporate fax)**
E-mail: **jschoen@medinuclear.com**

Secondary contact: Russell King
Owner/Chairman, Medi/Nuclear & Healthline Medical
Telephone Number: (800) 321-5981 (corporate toll-free)
(626) 960-9822 (Los Angeles local)
Fax: (626) 960-8700 (corporate fax)

Note: Medi/Nuclear Corporation, Inc. markets the products it manufacturers to the nuclear medicine industry under its own name. However, it also markets some of the same products to the respiratory therapy industry under the name of its affiliate company, Healthline Medical. Both companies share the same building, facilities, staff and management team at the above-listed address. The Neb-90 will be private-labeled for Healthline Medical upon receipt of clearance to market.

2. DEVICE NAME:

Classification Name: Nebulizer (CAF), direct patient interface
Regulation: 21CFR868.5630
Proprietary Name: Healthline Neb-90™ Large Volume Medication Nebulizer (LVN), Hereinafter referred to as "Neb-90"

3. PREDICATE DEVICE:

Medi/Nuclear Neb-3A Patient Nebulizer (K915075)
Smiths Medical – DHD Health Flo-Mist [B&B Medical Technologies Inc. Hope Nebulizer (K980407]

DESCRIPTION OF DEVICE:

The Nebulizer is a single patient/single use device which is filled with a fluid, typically respiratory medication and connected to a gas source via flexible tubing. The nebulizer works by having a fluid come into contact with the stream of gas. The gas shatters the liquid into small particles. These particles then impact a baffle that further reduces the size of the particles. The majority of the larger particles settle inside the nebulizer as a result of gravity and inertia, returning the mist to liquid to repeat the nebulization process. The smaller particles are then administered as the patient inhales. The treatment is completed when the majority of liquid has been nebulized.

General Questions & Answers

Specific issues, as mentioned in "CDRH Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators; October 1, 1993" are addressed herewith:

	Question	Yes	No
1	Is the device life-supporting or life-sustaining?		x
2	Is the device an implant (short-term or long-term)?		x
3	Is the device sterile?		x
4	Is the device for single use?	x	
5	Is the device prescription use?	x	
6	Is the device for home use or portable?		x
7	Does the device contain a drug or biological product as a component?		x
8	Is this device a kit? *		x
9	Is the device software-driven?		x
10	Is the device electrically operated?		x
11	Are there applicable standards for this device to which conformance has been demonstrated in addition to those already mentioned (e.g., IEC, ANSF, ASTM, etc)?		x

*The Neb-90™ in of itself is not a kit; however it will be marketed as a component of a kit, ARK-1, LG-ARK-1, ARK-5, LG-ARK-5, AM-690A and AM-690P.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2008

Mr. Michael McPeck
Director, Aerosol Medicine
Medi/Nuclear Corporation, Incorporated
4610 Littlejohn Street
Baldwin Park, California 91706

Re: K080657
Trade/Device Name: Neb-90™ Large Volume Medication Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 19, 2008
Received: June 23, 2008

Dear Mr. McPeck:

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.

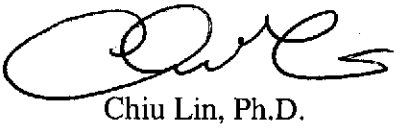
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Medi/Nuclear Corporation, Inc.
4610 Littlejohn Street
Baldwin Park, CA 91706-2267

Indications for Use Statement

510(k) Number K080657

Device Name: Neb-90™ Large Volume Medication Nebulizer

Indications for Use:

The Neb-90™ Large Volume Medication Nebulizer is indicated for the continuous aerosol administration of respiratory medication (inhalable solution) including, but not necessarily limited to, beta adrenergic bronchodilator (albuterol sulfate) and/or a wetting agent such as sodium chloride solution (saline) that is used for the treatment of respiratory and related diseases and conditions including, but not necessarily limited to asthma, COPD, bronchiolitis and cystic fibrosis.

The Neb-90™ Large Volume Medication Nebulizer is for use in hospital Emergency Department, ICU or other similar settings for delivery of aerosolized medication to patients undergoing severe respiratory distress.

Concurrence of CDRH, Office of Device Evaluation (ODE):

Prescription Use ____X_____ OR Over-The-Counter Use _____

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

510(k) Number: K080657