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510(k) SUMMARY
For
RediNeb® Small Volume Medication Nebulizer

JUL 25 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)
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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 *Redi*Neb® 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 *Redi*Neb® Small Volume Medication Nebulizer (SVN), Hereinafter referred to as "*Redi*Neb®"

3. PREDICATE DEVICE:

We hereby designate the Medi/Nuclear Neb-3A Patient Nebulizer (K915075) and Salter Labs Model 8660 NebuTech HDN Nebulizer (K962879) as predicate devices for the *Redi*Neb® medication Nebulizer. Medi/Nuclear will manufacture the *Redi*Neb® for its affiliate company, Healthline Medical, and the *Redi*Neb® will carry the Healthline brand name.

4. DESCRIPTION OF DEVICE:

The *Redi*Neb® is basically a miniaturized jet nebulizer, functioning very similarly to both of the predicate devices. Physical differences are that the maximum fill volume is 3 ml versus 6ml and design is such that the *Redi*Neb® can be incorporated with breath enhanced features of a manifold delivery body. The *Redi*Neb® nebulizer, though very small in size (creating minimal waste if used once and discarded), is fabricated of polymers such that it may be properly cleaned for reuse multiple times.

5. INDICATIONS for USE:

The Healthline *Redi*Neb® Small Volume Medication Nebulizer (SVN) is indicated to aerosolize medication approved for nebulization by a physician. The Healthline *Redi*Neb® Medication Nebulizer is intended for adult and pediatric patients consistent with the indications for aerosolized medication to or through the patient's pulmonary system.

The *Redi*Neb® Nebulizer device is for patient use in all areas where the administration of medication by aerosol means is warranted. This includes hospital/institutional settings, home care use, schools and long term care facilities.

6. SUBSTANTIAL EQUIVALENCE:

The Healthline *Redi*Neb® Medication Nebulizer is substantially equivalent to the Medi/Nuclear NEB-3A and the Salter Labs Model 8660 NebuTech HDN nebulizer devices.

7. TECHNOLOGICAL CHARACTERISTICS:

The Healthline *Redi*Neb® Medication Nebulizer operates with the same technology as the predicate devices. It is a jet nebulizer driven by air or oxygen. The basic technology of design is that the drive gas passes through the nebulizer's jet. The jet is covered by the venturi tube. The venturi tube is in close proximity to the jet causing a vacuum as the drive gas passes through the venturi tube which in turn causes the liquid to be drawn from the cup. As the liquid is drawn up, it is aerosolized as the liquid is accelerated by the drive gas. The aerosolized medication is then made available to the patient through a delivery device for inhalation.

8. SUMMARY OF TESTING:

Feature / Specification	Predicate		
	Salter NebuTech	Medi/Nuclear Neb-3A SVN	Healthline *Redi*Neb®
rticle Size (MMAD)	1.0 to 1.1 µm	0.8 to 1.2 µm	0.8 to 1.1 µm
rosol Generation Rate (AGR)	0.4 ml/min	0.3 ml/min	0.33 ml/min
ad Volume	.75 ml	.75 ml	.5 ml
ive Gas Flow rate	6-8 LPM Air or Oxygen	6-8 LPM Air or Oxygen	6-8 LPM Air or Oxygen
ended Use	Same	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2008

Mr. Jerry Schoen
Chief Operating Officer
Medi/Nuclear Corporation
4610 Littlejohn Street
Baldwin Park, California 91706

Re: K080969
Trade/Device Name: RediNeb® Small Volume Medication Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 22, 2008
Received: July 24, 2008

Dear Mr. Schoen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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.
Healthline Medical, Inc.
4610 Littlejohn Street
Baldwin Park, CA 91706-2267

Indications for Use Statement

510(k) Number K080969

Device Name: *Redi*Neb® Small Volume Medication Nebulizer

Indications for Use:

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Samuel Lin for CL.

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

510(k) Number: K080969

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

Prescription Use ___X___ OR Over-The-Counter Use _____