K082541

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SECTION V.

510(k) SUMMARY
Healthline MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System

NOV 2 6 2008

Manufacturer:	Medi/Nuclear Corporation, Inc. 4610 Littlejohn Street Baldwin Park, CA 91706
Regulatory Affairs Contact:	Jerry Schoen
Telephone:	(626) 960-9822
Date Summary Prepared:	August 22, 2008
Trade Name:	Healthline MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System
Classification:	Class II per 21CFR 868.5630
Predicate Device:	PARI LC Star Nebulizer K061381 and K963924
Description:	The MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System is a miniaturized nebulizer attached to a valved manifold. During patient inhalation, aerosol mist being generated from the nebulizer is substantially increased through Breath-Enhancement technology, and configuration is such that a filter can be added to the air exit port if so desired.
Intended Use:	The MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System is indicated to aerosolize medication approved for nebulization and prescribed by a physician. This Healthline MEDICATOR®/RediNeb® Aerosol Drug Delivery System is intended for adult and pediatric patients consistent with the indications for delivery of aerosolized medication to/or through the patient's pulmonary system. The MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System 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.
Substantial Equivalence:	Healthline MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System is substantially equivalent to the PARI LC Star nebulizer.
Summary of Testing:	All materials used in the fabrication of the Healthline MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System is currently in use in the manufacture of similar nebulizer devices and have FDA approval for this type application. Note table below.

Feature or Specification	Predicate PARI LC-Star	Healthline MEDICATOR®/RediNeb®
Particle Size (MMAD)	2.0 um	1.5 um
Aerosol Generation Rate (static)	0.26 ml/min.	0.23 ml/min.
Aerosol Generation Rate (enhanced)	0.38 ml/min.	0.42 ml/min.
Dead Volume	1.0 ml	0.72 ml
Drive Gas/Flow Rate	6-8 LPM (Air/Oxygen)	6-8 LPM (Air/Oxygen)
Intended Use	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2008

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

Re: K082541
Trade/Device Name: MEDICATOR® / RediNeb®
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: August 28, 2008
Received: September 2, 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) 276-0115. 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

Section IV.

Indications for Use Statement

510(k) Number (if known) K082541

Device Name: MEDICATOR®/*Redi*Neb® Aerosol Drug Delivery System is indicated to aerosolize medication approved for nebulization and prescribed by a physician. This Healthline medication nebulizer device is intended for adult and pediatric patients consistent with the indications for delivery of aerosolized medication to-or-through the patient's pulmonary system.

The MEDICATOR®/*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.

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

510(k) Number: K082541

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

Prescription Use ___X___ OR Over-The-Counter Use _____