DEC 30 2008

510(k) SUMMARY

Submitter's Name:
NSR Comercio e Representacoes Ltda
Av. Gupe, Bloco C Galpao 16
Jardim Belval
Barueri, SP 06422-120
Brazil

Owner Name:
Edvino Carbone
Phone#: (5511) 4619-2066
Fax#: (5511) 4619-2066

Contact Name:
Polly E. Scherman
NSR Trading LLC.
11 Perry Drive, Unit G
Foxboro, MA 02035
Phone#: 508-543-9300
Fax#: 508-543-9399

Date Prepared:
May 13, 2008

Product Classification:
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF

Nevoni Model Number:
Nevoni Classic 6600-PO

Purpose for Submission:
New device that has never been marketed in the US. The Nevoni Classic 6600-PO is packaged so that it is ready for consumer use.

Equivalent Marketed Predicate Devices:

Legally Marketed Predicate Device Registration #	**510(k)**
Invacare Model IRC 1001 Aerosol Compressor	K992643
Sunrise Medical Devilbiss Model 3655	K020932
Salter Labs Aire Compressor	K992285

Intended Use

The Nevoni Classic 6600-PO nebulizer is an ac powered portable compressor. This portable device uses a pneumatic piston that compresses air, forcing it to flow into the nebulizer cup. The force of the air flowing into the nebulizer cup disperses the medicine into fine mist particles for the inhalation treatment based on a physician's prescription. This device is intended for single patient home therapy.

Device Description:

The Nevoni Classic nebulizer is a portable AC-powered respiratory device used for home therapy. It uses a compressor to process medicine into a breathable aerosolized mist which is collected into a facial mask and inhaled by the patient.

The device's nebulization process is achieved through a small wired AC-electric motor that forces an oil-free piston into motion. This motion oscillates a sealed diaphragm and compresses air into a small chamber. Air intake is supplied to the compressor using a felt filter. The compressed air flow is conducted through a thin flexible tube into a nebulizer cup in which a fine particle mist is created by the medicine's highly pressurized contact. The nebulizer cup is attached to an anatomical mask made of soft, non-toxic material. The medicine's mist accumulates within this mask where it is ready for inhalation by the patient.

The Nevoni Classic nebulizer package includes a compressor, air tubing, air filters and adult and child size masks.

Substantial Equivalence:

The Nevoni Classic compressor is substantially equivalent to:

- Invacare Model IRC 1001 Aerosol Compressor
  FDA 510k Registration# K992643
- DeVilbiss Model 800
  FDA 510k Registration# K993492
- Salter Labs Salter Aire Compressor
  FDA 510k Registration# K992285

Comparative Product Table:

Product Properties	Nevoni Classic Model 6600-PO Compressor	Salter Aire Compressor	DeVilbiss Model 3655 Compressor	Invacare Model IRC 1001 Aerosol Compressor
Compressor type	Piston	Piston	Piston	Piston
Voltage	110V 50/60Hz 0.5 Amps	110V 60Hz 2.5 amps	110V 60Hz amps	115V 60 Hz 1.6 amps
Free flow rate	15 *lpm*	11 *lpm*	8 *lpm*	8.5 *lpm*
Operating flow ate	8 *lpm*	6.5 *lpm*	5.5 *lpm*	4.8 *lpm*
Over-heating switch	No	Yes	Yes	Yes
Portable	Yes	Yes	Yes	Yes
Case material	Plastic	Plastic	Plastic	Plastic
Warranty	1 year	1 year	5 year	5 year
Maximum operating temperature	158 °F	128.5 °F	104 °F	158 °F
Intended environment use	Home therapy	Home therapy and hospital	Home therapy	Home therapy

Substantial Equivalence Statement:

The Nevoni Classic compressor nebulizer is equivalent to FDA registered predicate marketed devices. These devices are similar in that they deliver medicine in the form of aerosol within acceptable parameters. The Nevoni Classic nebulizer delivers similar durability and performance as existing legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NSR, Comercio, Industria e Representacoes, Ltda
C/O Ms. Polly Scherman
Business Manager
NSR Trading LLC
11 Perry Drive, Unit G
Foxboro, Massachusetts 02035

Re: K082878
Trade/Device Name: Nevoni Classic 6600-PO
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: September 23, 2008
Received: October 1, 2008

Dear Ms. Scherman:

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

Indications for Use

510(k) Number K082878

Device Name: Nevoni Classic 6600-PO

Indications for Use:

The Nevoni Classic 6600-PO nebulizer is an ac powered portable compressor. This portable device uses a pneumatic piston that compresses air, forcing it to flow into the nebulizer cup. The force of the air flowing into the nebulizer cup disperses the medicine into fine mist particles for the inhalation treatment based on a physician's prescription. This device is intended for single patient home therapy.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

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

510(k) Number: K082878