MAY 2 8 2004

MEDICAL INDUSTRIES AMERICA INC.

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K032170

(2) TransNeb System 510(k) Summary

In accordance with 21CFR section 807.92, Medical Industries America Inc. is submitting the following summary.

Date June 26, 2003

Submitter Information

Medical Industries America Inc.
2636 289th Place
Adel, IA 50003
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Contact: Anne B. Carlson, Quality Systems Manager/Regulatory Affairs

Name of Device

Proprietary Name: TransNeb
Common Name: Nebulizer Compressor with Nebulizer
Classification Name: Nebulizer (Direct Patient Interface)

Substantially Equivalent to

Compressor: Omron Healthcare Inc.'s CompAir Elite K914836
Nebulizer: Pari LC Star K963924 & 56 Series Jet Nebulizer K021443

Device Description and Overview

The TransNeb system consists of a nebulizer and a DC powered piston-type compressor that generates compressed air. Small, lightweight and designed for convenience, the TransNeb device offers the user a choice of running off of AC power via a universal adapter or DC power via an option 12 volt auto adapter or an optional rechargeable battery pack. The device consists of a motor driven piston compressor, a printed circuit board and a switch. The circuit board does not incorporate a microprocessor but serves as a means to prevent double feed of power. The circuit board is not a part of the charging circuit for the battery pack.

The nebulizer, which employs a venturi effect to convert the medication into a fine aerosol mist, is used either snapped directly onto the compressor outlet barb or with an extension tube. Providing a connection between the compressor outlet barb and

the nebulizer bottom, the extension tube allows the user to place the compressor on a sturdy surface and to simply hold onto the nebulizer. The nebulizer is designed for single patient and is reusable. The nebulizer with or without its tubing adapter is designed specifically for use only with the TransNeb compressor. Use of the nebulizer, tubing or compressor with other compressors, nebulizers or tubing may produce incorrect flow resulting in improper treatment.

Both the TransNeb compressor and nebulizer and the predicate device's compressor are designed and manufactured by Medel S.p.A., Italy (Registration No. 8043860). Medel also manufactures the 56 Series Jet Nebulizer. The Pari LC Star is designed and manufactured by Pari Holding Co., Richmond, VA.

The TransNeb device has been designed and built according to the applicable requirements of IEC601-1 and meets the requirements the *Draft Reviewer Guidance for Premarket Notification Submission, November 1993.*

System Similarities and Differences to Currently Marketed Devices

Compressor

Both the TransNeb and the predicate device to which substantial equivalence is sought were designed to provide compressed air for the nebulizer to produce a fine aerosol mist. Both devices are primarily intended for the home care market.

Performance, as tested, is essentially equivalent to the predicate device and both products are the same basic size and weight. Other than basic form and dimensional differences between the TransNeb and the predicate device, there are virtually no major differences between the units in terms of function, performance or use.

Both devices are handheld and incorporate a reusable nebulizer. Both devices operate from 110-240V, 50-60Hz automatic switchable supply, offer optional car adapter and rechargeable battery, and come with a carrying case. Both devices offer a five year warranty on the compressor and six months on the battery. Improvements to the case design will make it possible to focus on the following TransNeb features: less vibration, an improved switch, feet which will allow the unit to be operated on its side without 'walking' across the surface, a solid battery fit, an improved filter cap and a tubing holder. The TransNeb compressor and nebulizer will also come with a quick start instruction card. The CompAir Elite notes 'shortened treatment times' and 'delivery of a dense aerosol that is breath enhanced' as key features of this device.

Nebulizer

Unlike the TransNeb nebulizer which designed for use only with the TransNeb compressor, the Pari LC Star nebulizer may be utilized with a variety of piston driven compressors currently available on the market. The TransNeb Nebulizer and the Series 56 Jet Nebulizer are manufactured from identical materials and with the same production processes.

Device

The TransNeb with nebulizer will be also be sold with the carrying bag, the AC adapter (power supply) with power cord, the tubing connector, five pack of filters, two mouthpieces, an extra nebulizer and the operator's manual with its quick start card. Optional accessories which will be offered this device are the DC cord with cigarette lighter adapter, and the battery.

The CompAir Elite is sold complete with the AC adapter (power supply) with power cord, nebulizer, mouthpiece, extra filters, carrying case, and instruction manual. Optional accessories for the CompAir Elite include the pediatric mask, the rechargeable battery pack, and car adapter.

Statement of Intended Use

The TransNeb compressor with nebulizer is a DC-powered piston compressor intended to provide a source of compressed air for use with a small volume nebulizer to produce a fine aerosol mist. The device must be prescribed by a physician. It is not intended for life support or life sustaining applications.

Comparative data

Compressor	Medical Industries America TransNeb	Omron Healthcare Inc. CompAir Elite
Pressure	36 PSI	36 PSI
Flow	5.2 LPM	4.5 LPM
Operating Pressure	10 PSI	10 PSI
Operating Flow	2.5 lpm	2 lpm
Noise Level	52 dBA	53 dBA
Type of Compressor	Piston	Piston
Input Power (power supply)	1.2A, 100-240VAC, 50-60Hz switching power supply	1.2A, 100-240VAC, 50-60Hz switching power supply
Supply Voltage	12V	12V
Case	ABS	ABS
Intake Filter	Yes – identical material different shape	Yes
Warranty	5 years – device; 6 months – battery	5 years – device; 6 months – battery
Eletromagnetic Compatibility	Conforms to IEC 601-1 and *FDA's Reviewer Guidance for Premarket Notification Submissions*	Conforms to IEC 601-1

Nebulizer	**TransNeb**	**Pari LC Star**
Particle Size Range	0.5 to 5 microns	0.5 to 7~9 microns
Capacity	7 ml (cc)	5 ml (cc)

Nebulizer	**TransNeb**	**56 Series Jet Nebulizer**
Molded Components	Polypropylene type Moplen HP500N	Polypropylene type Moplen HP500N

Conclusion

The TransNeb compressor with nebulizer, Model 5000, was tested for compliance with electrical, mechanical and environmental performance requirements for home use respiratory devices as found in *Reviewer Guidance for Premarket Notification Submissions November 1993* and with *Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators, October 1993*. In all instances the TransNeb compressor with nebulizer met the requirements and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Medical Industries America, Incorporates
c/o Mr. Ned E. Devine
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: K032170
Trade Name TransNeb Compressor with Nebulizer, Model 5000
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: II
Product Code: CAF
Dated: May 25, 2004
Received: May 27, 2004

Dear Mr. Devine:

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.

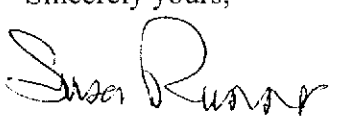
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.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

510(k) Number (if known): K032170

Device Name: TransNeb

Indications for Use:

The TransNeb compressor/nebulizer includes a DC powered air compressor that provides a source of compressed air for home health care use. The compressor is used with a venturi (pneumatic nebulizer) to convert certain inhaled drugs into an aerosol form for inhalation by a patient. The device can be used with adult or pediatric patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K032170

Prescription Use XX **OR** **Over the Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1/2/96)**