OCT - 7 2003

K031413

510(k) Summary
for the VigorMist COMPRESSOR NEBULIZER
(per 21CFR807.92)

1. SUBMITTER

Vega Technologies Inc.
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Date Prepared: January 03, 2003

2. DEVICE NAME

Proprietary Name: **VigorMist** Compressor Nebulizer
(Model: CN-01W)
K031413
Common/Usual Name: Compressor Nebulizer
Classification Name: Nebulizer (Direct patient interface)
Regulation Number: 21 CFR, 868.5630

3. PREDICATE DEVICE

- OMRON Compressor Nebulizer (K914836)
- VEGA Ultrasonic Nebulizer (k002831)

4. DEVICE DESCRIPTION

The VigorMist™ Compressor is a small air compressor designed to provide sufficient air pressure and flow to power a hand held nebulizer. It measures 11 7/8" x 7 1/8" x 4 1/2" and weights 4.6 lbs.

The device has a thermal protector that will automatically shut off the device when overheated. The operating components are located internally. The compressor, some minor wiring and exhaust/intake tubing are located inside.. External components include a switch, filter with housing, AC cord and cover or accessories compartment. The accessories coming with the compressor include a nebulizer, Air tube and mouthpiece.

5. INTENDED USE

The VigorMist™ Compressor is intended to be used with a compatible pneumatic nebulizer (specifically the WestMed VixOne) to convert certain inhalable drugs into an aerosol form for inhalation by a patient for the treatment of asthma, COPD, and other respiratory ailments. The device is intended for the home care market. It is intended for use with a single adult, pediatric, or infant patient.

6. PERFORMANCE TESTING

Testing provided in this premarket notification includes biocompatibility, standards conformity.. The VigorMist™ successfully completed testing and demonstrates that the product fulfills performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 - 2008

Vega Technologies, Incorporated
C/O Mr. Tzu – Wei Li
Responsible Third Party Official
Center for Measurement Standards of Industrial Technology Research Institute
Bldg 16, 321 Kuang Fu Road Sec. 2
Hsinchu
TAIWAN 30042, R.O.C.

Re: K031413
Trade/Device Name: Vigormist Compressor Nebulizer (Model: CN-01W)
Regulation Number: 21 CFR 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI, CAF
Dated: September 18, 2003
Received: September 23, 2003

Dear Mr. Li:

This letter corrects our substantially equivalent letter of October 7, 2003.

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 (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 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 continue 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-***[see OC organization structure below for correct phone extension].*** 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 (240) 276-3150 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: K031413

Device Name: **VIGORMIST Compressor Nebulizer** (model: CN-01W)

Indications For Use:

The **VigorMist Compressor** is intended to be used with a compatible pneumatic nebulizer (specifically the WestMed VixOne) to convert certain inhalable drugs into an aerosol form for inhalation by a patient for the treatment of asthma, COPD, and other respiratory ailments. The device is intended for the home care market. It is intended for use with a single adult, pediatric, or infant patient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K031413

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)