NOV 24 1998

K982956

SPIROMETRICS
MEDICAL EQUIPMENT COMPANY
415 Rodman Road Auburn, Maine 04210

510(k) SUMMARY

Submitted by: New VED Inc. d.b.a. Spirometrics Medical Equipment Co.
415 Rodman Road
Auburn, ME 04210
207-784-0906, Fax 207-784-1481

Contact Person: Donald Henton, Official Correspondent
Date Prepared: August 21, 1998

- Classification Name: Diagnostic Spirometer
- Common or Usual Name: Diagnostic or Screening Spirometer
- Proprietary Name: Flowmate II PLUS
- Establishment Registration Number: 1720605
- Classification: Diagnostic Spirometers have been classified as Class II devices.
- Performance Standard: None applicable from FDA, used conformance with American Thoracic Society (ATS) 1994 Spirometry criteria

Spirometrics has been marketing flow sensing pneumotachs with models Flowmate, Flowmate LTE, and PC Flow + devices. This listed product is substantially equivalent to the Flowmate 2500LTE premarket notification number K954759, Flowmate 2500 premarket notification number K863953/A, and PC Flow + 3350 premarket notification number K900673 manufactured by Spirometrics, the Renaissance from Puritan Bennett premarket notification number K911143, and the Presto Flash Portable Spirometry System from Burdick Inc. premarket notification number K894997.

For a description of the device see Summary Exhibit 1.

Description of the device:

- Flow sensing pneumotach and base that measures differential pressure as air passes through it (the same principle as the Flowmate LTE, Flowmate, and PC Flow + devices)

- Desktop design molded from high impact UL rated ABS plastic
- Automatic calculations of test results, and best test selection based on American Thoracic Society (ATS) criteria
- Testing capabilities include; FVC, FEV1, FEV3, FEV1/FVC%, FEF.2-1.2, FEF25-75%, FEF75-85, PEF, FEF50, FIVC, FEF50/FIF50, PIF, MVV, Methacholine Challenge, and Lung Age
- Testing Capabilities: Capacity 10 Liters
  Volume Accuracy +/- 3%
  Max. Flow Rate +/- 16 L/s
  Back Pressure Less than 1.5 cm H2O
- Population Predicted Normals included: Composite
  Knudson - 1976
  Knudson - 1983
  Crapo (ITS)
  ECCS
  Hsu
  Lam
- Customization allows user to change report format, input temperature and barometric readings, and select internal / external printer and associated driver for printer selected
- Reports printed on thermal paper 112mm wide or standard 8 1/2 " x 11" paper
- Field calibration with a 1 to 9 Liter calibration syringe
- Cross-contamination control via external filter system

Intended use for the Flowmate II PLUS is for Pulmonary Function Testing (measuring a person's ability to move air into and out of their lungs). The volume and flow rates measured for the effort and then reported as numerical results with a printout of the results if selected.

Waveform performance testing was conducted using a Pulmonary Waveform Generator (PWG), and showed that the Flowmate II PLUS exceeded the ATS recommendations for FVC, FEV1, FEF 25-75 and PEF accuracy and precision at all of the 24, testing under Body Temperature Pressure Saturated with water (BTPS) (see Summary Exhibit 2), and the 26 PEF waveforms (see Summary Exhibit 5).

The exhale / inhale performance of the device was tested using exponential waveforms created by the PWG using the same exponential curve in both exhale / inhale maneuvers. FVC, FIVC, PEF and PIF were recorded from four progressively faster exponential waveforms, with the accuracy and precision compared against the known three (3) liter syringe inputs. See Summary Exhibit 3 & 4.

MVV testing with the PWG also showed acceptable results compared with the ATS criteria for accuracy and precision to the delivered values (See Exhibit 3 & 4).

EMC and safety testing has shown the device to meet the EN60601-1-2 for emmissions and immunity, and the IEC 601-1 and UL 2601 safety standard for medical equipment. See Summary Exhibit 6.

Our conclusion is that the Flowmate II PLUS is substantially equivalent to the predicate device the FlowmateLTE. It is also substantially equivalent to the Flowmate, PC Flow+, Renaissance, and Presto Flash Portable Spirometry System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1998

Mr. Donald Henton
Spirometrics Medical Equipment Company
415 Rodman Road
Auburn, ME 04210

Re: K982956
Flowmate II PLUS
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: October 30, 1998
Received: November 5, 1998

Dear Mr. Henton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K982956

Device Name: Flowmate II PLUS

The intended environments for use are hospitals, physician / clinician offices, and industrial health screening locations.

The intended patient population is from children to adults.

Indications For Use: Pulmonary Function Testing

Diagnostic

To evaluate symptoms, signs, or abnormal laboratory tests

- Symptoms: dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain
- Signs: diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles
- Abnormal laboratory tests: hypoxemia, hypercapnia, polycythemia, abnormal chest radiographs

To measure the effects of disease on pulmonary function

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use

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

510(k) Number

510(k) Number: K982956

Device Name: Flowmate II PLUS

Indications For Use: Pulmonary Function Testing - continued

Diagnostic - continued
- To screen individuals at risk of having pulmonary diseases
  - Smokers
  - Individuals in occupations with exposures to injurious substances
  - Some routine physical examinations
- To assess preoperative risk
- To assess prognosis (lung transplant, etc.)
- To assess health status before enrollment in strenuous phsical activity programs

Monitoring
- To assess therapeutic interventions
  - Bronchodilator therapy
  - Steroid treatment for asthma, interstitial lung disease, etc.
  - Management of congestive heart failure
  - Other (antibiotics in cystic fibrosis, etc.)
- To describe the course of diseases affecting lung function
  - Pulmonary diseases
    - Obstructive airways diseases
    - Interstitial lung diseases
  - Cardiac diseases
    - Congestive heart failure
  - Neuromuscular diseases
    - Guillain-Barré
- To monitor persons in occupations with exposure to injurious agents
- To monitor for adverse reactions to drugs with known pulmonary toxicity

Disability / Impairment Evaluations
- To assess patients as part of a rehabilitation program
  - Medical
  - Industrial
  - Vocational
- To assess risks as part of an insurance evaluation
- To assess individuals for legal reasons
  - Social Security or other government compensation programs
  - Personal injury lawsuits
  - Others

Mark Kramer

510(k) Number: K982956

Indications For Use: Pulmonary Function Testing - continued

Public Health
Epidemiologic surveys
- Comparison of health status of populations living in different environments
- Validation of subjective complaints in occupational / environmental settings

Derivation of reference equations

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1. American Thoracic Society. 1995. Standardization of Spirometry 1994 Update. *Am. J. Respir. Crit. Care. Med.* 152:1108.