K954759

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: October 10, 1995

- Classification Name: Diagnostic Spirometer
- Common or Usual Name: Diagnostic or Screening Spirometer
- Proprietary Name: Flowmate LTE
- Establishment Registration Number: 1720605
- Classification: Diagnostic Spirometers have been classified as Class II devices.
- Performance Standard: None applicable

Spirometrics has been marketing a flow sensing pneumotach with its models Flowmate and PC Flow + . The proposed product is substantially equivalent to the Flowmate 2500 premarket notification number K863953/A, and PC Flow + 3350 premarket notification number K900673 both manufactured by Spirometrics, the Renaissance from Puritan Bennett premarket notification number K911143, and the Flash Portable Spirometry System from Tamarac Systems Corporation premarket notification number unkown.

For a description of the device see 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, PC Flow +, Renaissance, and Flash devices)
- Compact design molded from high impact UL rated ABS plastic, rechargeable Ni-Cad batteries for portable operation,
- Automatic calculations of test results, and best test selection based on 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
  Crapo (ITS)
  ECCS
  HSU
- Customization allows user to change report format, input temperature and barometric readings, and select printer driver for printer being used
- Reports printed on 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 LTE 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 entire effort and then reported as numerical results with a printout of the effort if selected.

Waveform performance testing showed that the Flowmate LTE exceeded the ATS recommendations for FVC, FEV1, FEF 25-75 and PEF accuracy at all of the 24 waveforms except #17. Waveform #17 takes over 20 seconds to complete. The Flowmate LTE accumulates volume for up to 15 seconds the same as the Flowmate 2500. Therefore, some of Waveform #17's volume was produced after the Flowmate LTE stopped recording data from the effort, which accounts for the variation between the actual delivered volume and the measured volume (See Exhibit 2). Taking the volume at the 15 second mark generated by waveform #17 (5.662 Liters) the accuracy is within the ATS recommendation at - 1.8%.

MVV testing used a 2 Liter volume at flow/rates from 40 to 245 L/M also showed acceptable results compared with the ATS criteria for accuracy and precision to the delivered values (See Exhibit 3).

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