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Section 8. Summary of Safety and Effectiveness.
The Static and Dynamic Compliance software product option is identical in safety and effectiveness to the predicate devices listed in the last section. The technique of placing an esophageal balloon and derived measurements are also the same as the predicate devices.

Static and dynamic compliance are measurements of pulmonary function, also commonly referred to as Respiratory Mechanics. The mechanical properties of the respiratory system are important to breathing effectively. In healthy people, the elastic recoil and compliance of the lung are easily managed by the respiratory muscles allowing normal breathing. In some common respiratory diseases, there are changes in recoil and compliance. Static and dynamic compliance are easily measured and can be valuable in determining the effects of lung disease on breathing.

Static and dynamic compliance are performed by having the patient swallow an esophageal balloon that is connected to a calibrated pressure transducer. The patient breathes quietly on a mouthpiece connected to a flow meter, while mouth pressure, esophageal pressure, flow rate and volume changes are measured. The balloon is placed in the esophagus just above the diaphragm. This position is determined by having the patient breath through a flow meter, while the operator views a display of esophageal pressure, inspiratory flow and expiratory flow on a computer monitor. The operator looks for a negative pressure-tracing concomitant to a positive flow tracing. If the pressure tracing is positive, the balloon has passed the level of the diaphragm and needs to be pulled back until a positive tracing is displayed.

When measurements are made under no-airflow conditions, Static Compliance is calculated. When the measurements are made under flow conditions, Dynamic Compliance is calculated.

Calculated Parameters are as follows.

Cst	L/kPa	Static Compliance	The change in volume/Trans-pulmonary pressure measured from FRC + 500 mls to FRC against a closed breathing valve
Ptp	CmH_2O	Trans-pulmonary Pressure	Mouth Pressure – Esophageal Pressure
Cdyn	L/kPa	Dynamic Compliance	Change in Volume/Trans-pulmonary pressure measured during quiet breathing
f	/min	Breathing Frequency	Breaths/minute
Vt	Mls	Tidal Volume	Inspiration or Expiration at Rest
MV	Min	Minute Ventilation	Vt * f

Normal Ranges for Compliance.

Males	Cst = 0.0024 *Age + .00516 * Height – 0.677
Females	Cst = 0.0019 *Age + .0039 *Height – 0.471

Reference: Begin, et. al. Flow and age dependence of airway closure and dynamic compliance. J. Appl. Physio. 38:199, 1975

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1998

Mr. Larry Murdock
SensorMedicss Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K981366
Static and Dynamic Compliance
Regulatory Class: II (two)
Product Code: 73 BTY
Dated: August 8, 1998
Received: August 10, 1998

Dear Mr. Murdock:

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

Section 9. Indications for Use.

The indications for use are the same as the Vmax Series to which this product is an option. Quotation from the Indications for Use section of the Vmax premarket notification: "Basically, this involves performing physician-prescribed pulmonary function and metabolic testing. More-specific intended uses are shown in the table below, along with the predicate SensorMedics product model with the same intended-use labeling."

(This table is from the Vmax premarket notification)

Intended Use	Same As	Similar To	Different From
Differential diagnosis (heart/lungs)	2900		
Disability assessment	2900		
Rehabilitative evaluation	2900		
Exercise prescription	2900		
Sports medicine/research	2900		
Energy assessment, substrate utilization	2900		
Assessment or supplemental O2 requirement	2900		
Evaluation of medication effects	2900		
Pulmonary Function testing for adults & children	2200		
Document effectiveness of bronchodilator therapy	2200		
Pulmonary disability evaluation	2200		
Industrial surveillance	2200		
Broncho-challenge testing	2200		
Exercise induced bronchospasm	2200		
Pre-surgical risk evaluation	2200		
Bedside lung function	2200		

The Static and Dynamic Compliance option is indicated specifically for Evaluation of medication effects, Pulmonary Function testing in adults & children, Pulmonary disability evaluation, Industrial surveillance and Bedside lung function.

Lee Mador 10-29-98

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

510(k) Number

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