



JUL 30 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

VIASYS Healthcare GmbH
C/O Mr. Earl Draper
Director Quality Systems & Regulatory Affairs
SensorMedics, Incorporated
22705 Savi Ranch Parkway
Yorba Linda, California 92887-4645

Re: K031194

Trade/Device Name: SpiroSoft
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: BTY
Dated: June 25, 2003
Received: June 30, 2003

Dear Mr. Draper:

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.

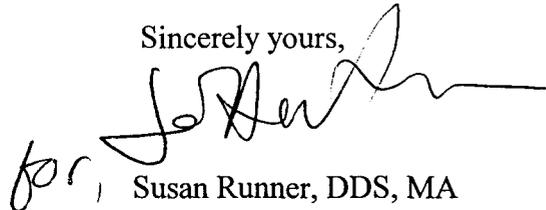
Page 2 – Mr. Draper

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,

for, Susan Runner, DDS, MA

Interim 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: K031194

Device Name: SPIROSOFT

Indications For Use:

The SpiroSoft is a portable device and can be used by physicians in the office or hospital and in occupational medicine.

The SpiroSoft measures inspiratory and expiratory lung function parameter in adults and children from 4 years on according to the ATS recommendations for diagnostic devices.

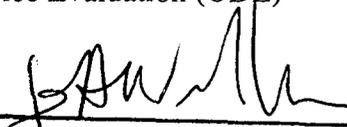
Results are output graphically and numerically on a screen and on an external printer. SpiroSoft saves all data in the internal memory for later retrieval or printout.

The following caution label appears on page 2 of the SpiroSoft Instruction Manual: "Federal U.S. law restricts this device to sale by or on the order of a physician."

April-03-2003
Dr. Jürgen Reinstädler
(Product Manager)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K031194

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)