OCT 28 1998

510(k) SUMMARY

MANUFACTURE'S ADDRESS:	Mailing - PO Box 47304 Facilities - 14030 23rd Ave. North Plymouth, MN 55447
PHONE NUMBER:	(612) 559-8492
FAX NUMBER:	(612) 559-2961
CONTACT:	Kevin J. Driscoll, Quality Assurance, Regulatory Affairs Ext: 924
TRADE NAME:	SpiroCard
CLASSIFICATION NAME:	Diagnostic Spirometer
CLASSIFICATION:	Class II, according to 21 CFR, 868.1840
MODIFICATION OF:	510[k] #K932278, Advanced Medical Systems Corp. PFM Professional 7000

DEVICE SUMMARY:

The SpiroCard is a spirometery diagnostic device that measures the breathing functions of patients. The volume and rate of exhalation and inhalation is measured and calculated by the spirometer. Information provided by the spirometer assists the physician in diagnosing and treating respiratory diseases.

The SpiroCard uses the same pneumotachometer mouthpiece and connecting tube as the predicate device so that no new materials are introduced to the patient. The SpiroCard measures and calculates the results the same as the predicate device using the pressure produced by the pneumotachometer, the same correction factors and formulas for final results. The pressure sensor is the same type but in a smaller package and of higher resolution and accuracy.

The main difference is that the SpiroCard is in a PC Card package and that the reporting and user interface will be completely handled by a host computing device whereas the PFM-7000 was a desktop standalone device with a keypad, processor and displays built in.

TESTS: The SpiroCard and the predicate device were both tested using a Pulmonary Waveform Generator that produced American Thoracic Society Standard waveforms. The results of both tests supported substantial equivalence and met specifications.

INTENDED USE: To be used as a Diagnostic Spirometer, measuring FVC, MVV and SVC breathing functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1998

Mr. Kevin J. Driscoll
QRS Diagnostic, LLC
14755 27th Avenue North
Plymouth, MN 55447

Re: K973138
SpiroCard
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: July 31, 1998
Received: August 5, 1998

Dear Mr. Driscoll:

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

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: K973138

Device Name: SpiroCard

Indications for Use:

- Diagnostic Spirometry
  - *Patient Population:* Male/Female, Pediatric to Adult
  - *Device Functionality:* Diagnostic Spirometry
  - *Spirometric Parameters:* FVC, MVV, SVC, and FEF
  - *Environment of Use:* Hospital, Clinical and Home Use
  - Prescription device by a physician

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lark Mathis 10-28-98

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

Prescription Use ✓ OVER-THE-COUNTER USE ____
(optional Form 1-2-96)