Attachment VII.

SMDA Summary of Safety and Effectiveness Information

In compliance with requirements of the Safe Medical Device Act (SMDA) of 1990, the following information is submitted as a summary of safety and effectiveness information for this 510(k) premarket notification:

1.   **Predicate Device Identification:**   A claim of substantial equivalence of the Vacu•Med, Gold Edition, Oxygen Gas Analyzer is made to the:

   •   PHYSIO-DYNE Easi-Lab, K922660.

This device was marketed after May 28, 1976 and has received FDA clearance to market since that date.

2.   **Statement of Biocompatibility.**

   The Vacumetrics Gold Edition Oxygen Gas Analyzer is a device that incorporates a Vacu•Med designed oxygen gas analyzer housing, with a commercially available oxygen paramagnetic gas analyzer (Servomex 1155B), a commercially available power supply (Condor), and other commercially available components to include a commercially available digital meter display which does not utilize any software.

   Environmental testing has been performed for the intended use for this device; a summary of the tests and results is included in Attachment V.

3.   **Comparative Information Summary of Functionality/Performance:**

   Functional / Performance Comparison of Vacu•Med, Gold Edition Oxygen Gas Analyzer, product code 17518A, and PHYSIO-DYNE Easi-Lab, product code XXXX .

   Test results: A comparative performance test of the Vacumetrics Gold Edition Oxygen Gas Analyzer to the PHYSIO-DYNE Easi-Lab Gas Analyzer was completed.   The purpose of the test was calibration verification.   Under conditions of the test, the data shows that the calibration accuracy of the Vacumetrics Gold Edition Oxygen Gas Analyzer is equivalent to the accuracy of the PHYSIO-DYNE Easi-Lab Gas Analyzer.

   It may be concluded that in terms of analyzing accuracy, the Vacumetrics Gold Edition Oxygen Gas Analyzer is substantially equivalent to the PHYSIO- DYNE Easi-Lab Gas Analyzer.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 1998

Vacumetrics Inc./Vacu•Med Division
c/o Ms. Rae Nadine Smith
Drug & Device Clinical Services, Inc.
2225 East Murray Holladay Road, Suite 207
Salt Lake City, UT 84117

Re: K973545
      Vacu•Med Gold Edition Oxygen (O_2) Gas Analyzer
        Model 17518A
      Regulatory Class: II (two)
      Product Code: 73 CCL
      Dated: February 26, 1998
      Received: February 27, 1998

Dear Ms. Smith:

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 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
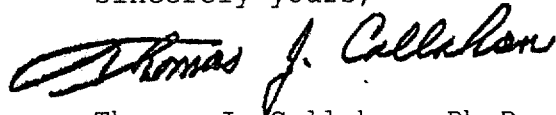and adulteration.

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/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

K973545

510(k) Number (if known): __New Submission__

Device Name: Gold Edition VacuMed Oxygen Gas Analyzer

Indications for Use:

The indications for use of the Gold Edition VacuMed Oxygen Gas Analyzer are to measure expired Oxygen Gases.

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

Concurrence of DCRH, Office of Device Evaluation (ODE)

Prescription Use __✓__   OR   Over-The-Counter Use_____
(per 21 CFR 801.109)   (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number___K973545____