

K973544

MAY 26 1998

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, Carbon Dioxide 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. Biocompatibility Assessment: 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. Summary of Comparative Information:

Functional / performance Comparison of Vacu•Med, Gold Edition Carbon Dioxide Gas Analyzer, product code 17515A, and PHYSIO-DYNE Easi-Lab, product code XXXX was performed.

Test results: A comparative performance test of the Vacumetrics Gold Edition Carbon Dioxide 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 Carbon Dioxide Gas Analyzer is equivalent to the accuracy of the PHYSIO-DYNE Easi-Lab Gas Analyzer.

CONCLUSION

The Vacu•Med, Gold Edition Carbon Dioxide Gas Analyzer functions well in the measurement of expired CO₂ gases with an accuracy of 0.1% CO₂. 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.



MAY 26 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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: K973544
Vacu•Med Gold Edition Carbon Dioxide (CO₂) Gas Analyzer
Model 17515A
Regulatory Class: II (two)
Product Code: 73 CCK
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 (Pre-market 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.

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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

510(k) Number (if known): New Submission

K973544

Device Name: Gold Edition Carbon Dioxide Gas Analyzer

Indications For Use:

Intended for measuring the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Poyard
for WYS 5/26/98
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

OR

Over-The-Counter Use _____

Prescription Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)