DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 1998

Mr. Leo den Bakker
Erich Jaeger B.V.
Regulierenring 11
NL-3981 LA Bunnik
THE NETHERLANDS

Re: K980094
OxyconAlpha, Modified with Windows 95 System
Regulatory Class: II (two)
Product Code: 73 BTY
Dated: April 28, 1998
Received: May 1, 1998

Dear Mr. Bakker:

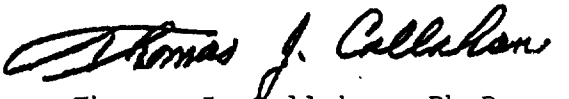
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

510(k) Number (if known): **K980094**

Device Name: **OxyconAlpha, Modified with Windows 95 system**

Indications For Use:

The OxyconAlpha is used as a predictive pulmonary function value calculator (Product code BTY). It is a software-driven, active medical device for investigational exercise measurements. It measures the human response to increasing workloads with emphasis on the gas exchange parameters. Measurements include ventilation, oxygen uptake, carbon dioxide production and derived parameters.

It is the intention to determine on patients a cardiopulmonary limitation and to test on sport athlets their training level. The different load levels for both groups can be generated over a bicycle ergometer or over a treadmill. The patient population is age 4 and older. The environment of use is indoor.

The OxyconAlpha interfaces to a testsubject via mouthpiece or a face mask. The OxyconAlpha interfaces to peripheral equipment and is therefore available in a variety of configurations from a standard controlled ergospirometry unit to a fully expandable laboratory system with blood pressure monitor, treadmill and ergometer. The OxyconAlpha interacts with the ECG signal (recorded by another device) only to the extent of extracting the patient's heart rate from the ECG signal. Other uses such as displaying or further analyzing the ECG waveforms are not included in the present submittal.

The device is not intended for use as a diagnostic pulmonary-function interpretation calculator.

(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 Cardiovascular, Respiratory,
and Neurological Devices

Prescription Use ✓ 510(k) Number _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)