K974200

JUL 21 1998

Attachment 2

# 510(k) Summary
# ORCA Cardiopulmonary Exercise Testing System
# ORCA Diagnostics Corporation
**July 18, 1998**

Product Name: Current Trade Name: ORCA Cardiopulmonary Exercise Testing System.™

Generic Name: Cardiopulmonary exercise or stress testing equipment

Classification Name: Calculator, pulmonary function interpreter; 21 CFR 868.1900, classification code BZM and Calculator, predicted values, pulmonary. Function, 21 CFR 868.1890, code BTY, both designated as Class II devices

Contact Person: Sheila W. Pickering Ph.D.
P.O. Box 1951
Los Altos, California 94123
Telephone/Fax 650 969 6114

**A. Legally Marketed Predicate Device**

The ORCA Cardiopulmonary Exercise Testing System is substantially equivalent to the MedGraphics Exercise Consult (K923209) manufactured by Medical Graphics, Inc, and the Vmax 229 Series, Pulmonary/metabolic System (K942211) manufactured by Sensormedics, Inc., which are both hardware and software devices. The ORCA device is substantially equivalent to the predicate devices with regard to device features and specifications, as well as intended use. All devices are cardiopulmonary exercise/stress evaluation systems with similar operating requirements. The application is based on standard clinical procedures.

**B. Device Description**

The ORCA Cardiopulmonary Exercise Testing System is a self-contained unit designed to provide patient respiratory gas exchange data during exercise stress testing. The system consists of components which measure the flow of exhaled air, and analyze the oxygen and carbon dioxide content of the exhaled air. A transcutaneous pulse oximeter reports heart rate and oxygen content of the arterial blood. Instruments are interfaced to a Pentium-based personal computer through a 16 channel, 12 bit analog/digital converter. As an option, information can be integrated with electrocardiographic information provided by external EKG equipment (EKG equipment is not provided with the ORCA system). Software collects and analyzes data, summarizes results and suggests possible implications of abnormalities observed.

**C. Intended Use**

The ORCA System is indicated for use in exercise tests where the collection and analysis of gas exchange and extraction of pulse rate information from ECG during exercise stress testing is needed. Further, the device will suggest interpretive statements based on the results of the analysis and the reasons for the test termination. The intended patients are adults and children and the intended environment of use is indoors. The ORCA System Product Manual provides warnings and precautions regarding intended use, detailed information on system operation, and further information on interpretive features.

**D. Substantial Equivalence**

The following tables show the basis for substantial equivalence

## Substantial Equivalence Comparison Table

| | Predicate Devices | | Submission Device |
|---|---|---|---|
| Product Name | Medgraphics CPX/D K923209 | Sensormedics Vmax 229 K942211 | ORCA Diagnostics |
| Intended Use* | Collection and analysis of gas exchange and extraction of pulse rate from ECG during stress testing | Collection and analysis of gas exchange and extraction of pulse rate from ECG during stress testing | Collection and analysis of gas exchange and extraction of pulse rate from ECG during stress testing |
| Intended Users | Pulmonologists, Cardiologists and Sports Medicine physicians | Pulmonologists, Cardiologists and Sports Medicine physicians | Pulmonologists, Cardiologists and Sports Medicine physicians |
| Intended Population | Not specified in labeling | Not specified in labeling | Adults and children referred for stress testing |
| Site of Use | Cardiology, Pulmonary and Sports Medicine clinics and physician offices; Hospitals | Cardiology, Pulmonary and Sports Medicine clinics and physician offices; Hospitals | Cardiology, Pulmonary and Sports Medicine clinics and physician offices; Hospitals |
| Measurements | Expired concentration of $O_2$ and $CO_2$, expired air flow, $O_2$ saturation, pulse rate | Expired concentration of $O_2$ and $CO_2$, expired air flow, $O_2$ saturation, pulse rate | Expired concentration of $O_2$ and $CO_2$, expired air flow, $O_2$ saturation, pulse rate |
| Patient Interfaces | ECG electrodes, disposable pneumotach, pulse oximeter | ECG electrodes, disposable pneumotach, pulse oximeter | ECG electrodes, disposable pneumotach, pulse oximeter |
| Accessories | Integrated gas calibrator | Integrated gas calibrator | Integrated gas calibrator |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1998

ORCA Diagnostics, Inc.
c/o Sheila W. Pickering, Ph.D.
P.O. Box 1951
Los Altos, CA 94019

Re: K974200
ORCA Cardiopulmonary Exercise Testing System
Regulatory Class: II (two)
Product Code: 73 BZM
Dated: June 24, 1998
Received: June 26, 1998

Dear Dr. Pickering:

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/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

FDA Submission Cover Sheet

510(k) Number (if known): K974200

Device Name: ORCA Cardiopulmonary Exercise Testing System

Indications For Use:
The ORCA System is indicated for use in exercise tests where the collection and analysis of gas exchange and extraction of pulse rate information from ECG during exercise stress testing is needed. Further, the device will suggest interpretive statements based on the results of the analysis and the reasons for the test termination. The intended patients are adults and children and the intended environment of use is indoors.

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

Mark Kramer Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR 801)