MAR 2 8 2003

K023565

510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

January 22, 2003

Caradyne, Ltd.
Parkmore Business Park
Parkmore West
Galway, Ireland

Tel 011 (353) 91-709010
Fax 011 (353) 91-758929

Official Contact: John, O'Dea, PhD – General Manager
Proprietary or Trade Name: OxiCheck
Common/Usual Name: Oxygen analyzer
Classification Name: Analyzer, Gas, Oxygen, gaseous phase
Predicate Devices: Ceramatec – Handi – K973282
Caradyne – Criterion 60 – K000959

Device Description:

The OxiCheck is a disposable oxygen analyzer that checks the oxygen concentration (also called fractional inspired oxygen, FiO_2) of a delivered air/oxygen mixture.

Intended Use:

The OxiCheck is intended as a tool for use by qualified personnel to check or measure oxygen concentration of a delivered air / oxygen mixture.

The OxiCheck is not intended for use in breathing systems and is not intended for patient monitoring. It is not intended to be used to continuously monitor or confirm oxygen delivery to a patient.

Environment of Use:

Intended for use in Hospitals, Sub-acute Institutions, Transport, and Home care settings.
The OxiCheck is not intended for use in a MRI environment.

General Technical Characteristics

Attribute	**Caradyne - OxiCheck – Proposed device**
Indications for use	The OxiCheck is intended as a tool for use by qualified personnel to check or measure oxygen concentration of a delivered air / oxygen mixture. The OxiCheck is not intended for use in breathing systems and is not intended for patient monitoring. It is not intended to be used to continuously monitor or confirm oxygen delivery to a patient.
Disposable	Yes
Prescription	Yes
Intended Environment of Use	Hospitals, Sub-acute Institutions, Transport, Home care. The OxiCheck is not intended for use in a MRI environment.
Design and Specifications	
Measurement range	0 to 100% O_2.
Display resolution	1% O_2.
Response time	< 10 seconds to 90% of final value.
Linearity error	< 3% of reading.
Drift	< 1% O_2 over 8 hours.
Humidity influence	< 1% O_2 between 0 and 95% RH at 25°C.
Pressure influence	Proportional to changes in atmospheric pressure.
Operating temperature	0 to 50°C.
Temperature compensation	Integral NTC compensation.
Operating humidity	0 to 95% RH.
Storage temperature	-20 to 60°C in supplied shipping container.
Recommended storage temperature	5 to 15°C.
Battery power indicator	Device powers off when battery is depleted.
Analyzer life	500,000 oxygen hours (15 months continuous use at 45% O_2 or 5000 hour at 100% O_2).
Weight	~ 90 gram
Materials	
In-line tee – PVC	Yes – Same material as Criterion 60 – K000959
Performance Standards	
None under Section 514	Yes
ASTM F1462-93 – Specification for Oxygen Analyzers	Complies to applicable sections
ISO 7767:1997 – Oxygen Monitors for Monitoring Patient Breathing Mixtures – Safety Requirements	Complies to applicable sections
ISO 5356 – 15 / 22 mm Conical fittings	Complies

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

Caradyne Limited
C/O Mr. Paul Dryden
ProMedic, Incorporated
6329 West Waterview Court
McCordsville, Indiana 46055-9501

Re: K023565
Trade/Device Name: OxiCheck
Regulation Number: 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: January 22, 2003
Received: January 23, 2003

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K023565 (To be assigned)

Device Name: OxiCheck

Intended Use: The OxiCheck is intended as a tool for use by qualified personnel to check or measure oxygen concentration of a delivered air / oxygen mixture.

The OxiCheck is not intended for use in breathing systems and is not intended for patient monitoring. It is not intended to be used to continuously monitor or confirm oxygen delivery to a patient.

The OxiCheck is intended to be used in hospitals, Sub-acute Institutions, Transport, and Home care.

The OxiCheck is not intended for use in a MRI environment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023565