JUL - 9 1999

K984295

510(k) SUMMARY (*Revised 4/15/99*)

Invacare Corporation's
CHECK O_2 PLUS OXYGEN ANALYZER

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director , TQM and Regulatory Affairs

Date Prepared: November 30, 1998

Name of Device and Name/Address of Sponsor

Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name

Oxygen Analyzer

Classification Name

Oxygen Gas Analyzer

Predicate Devices

The Invacare Check O_2 Plus is substantially equivalent to the Puritan Bennett Corporations' Model "Companion ROCI (K920338)."

Intended Use

The Invacare Check O2 Concentrator Analyzer device is a tool for use by service personnel to evaluate the output of an oxygen concentrator. Its intended use is to provide information to the service technician regarding oxygen content, flow rate, and pressure, of oxygen produced by an oxygen concentrator. It is not intended to be used by patients who are prescribed oxygen, nor is it intended to continuously monitor or confirm oxygen delivery to patient.

Intended Environment: The Check O2 is intended to be used in an environment where Oxygen Concentrators are serviced or repaired. This includes Hospitals, Nursing Homes, Extended Care Facilities, Patient Homes and Respiratory Device Service and Repair Centers.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Check O_2 Plus is a lightweight, battery powered device which measures oxygen gas concentration, flow and pressure from an oxygen concentrator. The device is a standalone product and does not have any accessories, power supply adapters or fittings. This device is intended as a tool for use by oxygen concentrator service personnel, to evaluate the output of an oxygen concentrator. It is not intended to be used by patients who are prescribed oxygen, nor is it intended to continuously monitor or confirm delivery of oxygen to a patient.

The device connects to an oxygen concentrator through existing therapy tubing presently in use throughout the industry. The device is designed and calibrated for use only on the species mixture inherent with the output flow of a concentrator. Information provided is the concentrator's oxygen concentration, flow and pressure. Continuous monitoring of output gas flow between an operating concentrator and a patient is not possible. Use with any downstream devices or patient accessories is also not possible.

It is further intended that this device be used on clean, dry and unhumidified concentrator output gas. In conjunction with the operating temperature of oxygen concentrators, the ambient temperature range of the Check O_2 Plus is within the range of +10 to +35 degrees Celsius and should remain in a dry indoor environment.

The concentrator gas is expected to fall within the following ranges and will be measured with the accuracy's listed below.

Concentration:	73% to 95.6% oxygen, ± 2%
Flow:	0 to 6 Liters per minute, ± 0.3 L/M (5% of full scale) ± 1 digit
Pressure:	0 to 10 PSI, ± 2% full scale
	0 to 68.95 kPa, ± 2% full scale

A. Substantial Equivalence

The Invacare Check O_2 Plus covered by this submission is substantially equivalent to other legally marketed oxygen analyzer devices. Specifically, the Invacare **Check O_2 Plus** is substantially equivalent to **the Puritan Bennett Corporations' Model "Companion ROCI" (K920338 8/27/92).** The Invacare Check O_2 Plus is comparable this device in several aspects.

The Invacare Check O_2 Plus has the same intended use, principle of operation and technological characteristics. Both devices are battery powered and have similar performance characteristics, features and specifications for accuracy of measured output. Finally, both sensors utilize ultrasonic technology for measuring oxygen concentration. This is a proven technique for measuring oxygen concentration as a function of gas density.

The Check O_2 Plus differs from its predicate device in that it has the capability of measuring pressure and flow, as well as oxygen content. As such it is a more complete tool for use in analyzing concentrator output and measuring concentrator performance. Additionally, the Check O_2 Plus device measures oxygen content within the range of $\leq$ 73% to 95.6%, while the predicate device measure oxygen concentrator output in the $\leq$ 70 to $\leq$ 85% range.

The Invacare Check O_2 Plus differs from the Puritan Bennett device in that the Puritan Bennett device is designed as an optional retrofittable upgrade for an oxygen concentrator, that continuously monitors oxygen content, and informs the concentrator user whether oxygen purity is within acceptable ranges. This differs from the Invacare device, which is intended only as a tool for measuring concentrator output performance, and not as a means of continuously monitoring oxygen purity levels.

Although there are some differences between the Check O2 and its predicate device, these differences are minor and raise no new questions of safety and effectiveness. We believe, therefore, that the Invacare Check O_2 Plus is substantially equivalent to the predicate device referenced in this submission, and trust that the information provided will be sufficient to enable FDA to find the Invacare Check O_2 Plus substantially equivalent to the predicate device.

Performance Data

The Invacare Check O_2 Plus was tested in accordance with the electrical, mechanical and environmental performance requirements for home use respiratory devices set forth in the Anesthesiology and Respiratory Devices Branch's November 1993 document entitled "Reviewer Guidance for Premarket Notification Submissions". In all instances the Check O_2 Plus met the required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL -9 1999

Mr. Edward A. Kroll
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, OH 44036-2125

Re: K984295
Invacare Corporation's Model Check 02 Plus Concentrator Analyzer
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: April 15, 1999
Received: April 19, 1999

Dear Mr. Kroll:

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): *K984295 (Revised 4/15/99)*

Device Name: Invacare Check O2 Concentrator Analyzer

Indications For Use:
The Invacare Check O2 Concentrator Analyzer device is a tool for use by service personnel to evaluate the output of an oxygen concentrator. Its intended use is to provide information to the service technician regarding oxygen content, flow rate, and pressure, of oxygen produced by an oxygen concentrator. It is not intended to be used by patients who are prescribed oxygen, nor is it intended to continuously monitor or confirm oxygen delivery to patient.

The Check O2 has measurement capability in the following ranges:
73% - 95.6% Oxygen Concentration
0 - 6 LPM Flow
0 - 10 PSI Pressure

Accuracy of the Device is:
± 2% Oxygen Concentration
± .3 L/M Flow (5% of full scale) ± 1 digit
± 2 PSI Full Scale Pressure
0 to 68.95 kPa, ± 2% Full Scale

Intended Environment: The Check O2 is intended to be used in an environment where Oxygen Concentrators are serviced or repaired. This includes Hospitals, Nursing Homes, Extended Care Facilities, Patient Homes and Respiratory Device Service and Repair Centers.

(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
510(k) Number K984295

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)