510(k) Summary JAN - 3 2008 K072469

- Trade name - DigiFLO Concentrator ANALYZER
- Common name - DigiHH
- Classification name - Oxygen gas analyzer (Product Code: CCL)

Equivalence claimed to:

- Invacare Check O_2 Plus **K984295**
- PRO2 CHECK OXYGEN INDICATOR **K983500.**

description of the device

The DigiFLO Concentrator ANALYZER is a lightweight, battery operated device, which measures oxygen concentrator outlet oxygen gas concentration and flow rate by means of ultrasonic wave, which travels from one piezoelectric transducer to another, and Oxygen pressure by means of a piezoresistive pressure transducer. The device is a standalone product and does not have any accessories, power supply adapters and fittings. The device is intended as a tool for use by oxygen concentrator service personnel, to evaluate the output and internal pressures in 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 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 gas mixture inherent with the output flow of a concentrator. Information provided by DigiFLO Concentrator ANALYZER is the concentrator's oxygen concentration, flow rate, and pressure. Continuous monitoring of output gas flow between an operating oxygen concentrator and the 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 DigiFLO Concentrator ANALYZER is within +10 to +40 degrees Celsius and should remain in dry indoor environment.

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

Flow Range	• Concentrator outlet: 0 to 20 Liters per Minute ±0.2 L/M • Air: 0 to 10 Liters per Minute ±0.2 L/M
Oxygen Content	20.8% to 95.7% oxygen ±1.8%
Pressure Range	0 to 35 PSI, ±0.5%
Battery	9V "N" type battery
Temperature range	+10°C to +40°C

Intended Use:

The DigiFLO Concentrator ANALYZER is a tool used by service personnel to measure Oxygen purity and Flow at the outlet of an oxygen concentrator. Also, it measures gas pressure inside and at the outlet 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 oxygen delivery to a patient.

Intended Environment: The DigiFLO Concentrator ANALYZER is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes Hospitals, Nursing Homes, Extended Care Facilities, Patient Homes, and Respiratory Device Service and Repair Centers.

"Caution:

The Federal Law restricts this device to sale by or on order of a physician, or any other practitioner licensed by the law of the state in which he practices to use or order the use of this device."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2008

Mr. Michael Stern
DigiFLO, Incorporated
6942 96th Avenue, SE
Mercer Island, Washington 98040

Re: K072469
Trade/Device Name: DigiFLO Concentrator ANALYZER
Regulation Number: 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: December 21, 2007
Received: December 28, 2007

Dear Mr. Stern:

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number **K072469**

Device Name: DigiFLO Concentrator ANALYZER

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Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

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

K072469