AUG 4 - 2005

K050430

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY"

9.1	Manufacturer:	Merits Health Products Co., LTD. 9, Road 36, Taichung Industrial Park Taichung, Taiwan R.O.C
9.2	Submitted By:	Contact – P/L Biomedical Lee Leichter 7690 Cameron Circle Fort Myers, FL 33912 Tel – 239-768-1118 Fax – 815-550-0162 Prepared – April 26, 2005
9.1	Trade/Proprietary Name:	Merits Health Products Oxygen Tank Filling Accessory
9.2	Common/Usual Name:	Oxygen Concentrator (Accessory)
9.3	Classification Name:	Portable Oxygen Generator

9.4 Comparison to Currently Marketed Devices

The modified Oxygen Concentrators are substantially equivalent to the currently marketed Invacare Corporation Model HomeFill II Complete Home Oxygen System (K003939).

9.5 Device Description

The Profill Q601 series home oxygen filling machines are prescription devices designed for use in home by patients that require supplemental oxygen. It is intended to pressurize oxygen from an oxygen concentrator to fill gas cylinders for the patient's personal ambulatory use. It is not intended for life support nor does it provide any patient monitoring capabilities.

The device consists of a compressor module and a portable oxygen cylinder with a specially adapted cylinder fitting. It is compatible with available standard oxygen concentrators as the source of oxygen. The oxygen generated by the oxygen concentrator is inducted into a buffer tank. Then it is split into two streams. The first stream flows to the outlet on the control panel. The patients can use this as their source of supplemental oxygen while they are filling their cylinders. The second stream flows to the compressor where the oxygen is pressurized and filled into the cylinder. The devices are not sold or labeled as sterile

9.6 Indications for Use

The Oxygen Concentrators with the Oxygen Filling accessory are indicated to provide supplemental oxygen to patients in the home and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended for life support nor does it provide any patient monitoring capabilities

9.7 Technological Characteristics

The technological characteristics are the same as the predicate devices.

9.8 Performance Data

Verification testing has confirmed the product meets its specifications.

9.9 Conclusion

Based on the design, performance specifications, testing and intended use, the Oxygen Filling Accessories are substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 - 2005

Merits Health Products Company
c/o Mr. Lee Leichter
P/L Biomedical
7690 Cameron Circle
Fort Myers, Florida 33912

Re: K050430
Trade/Device Name: Merits Health Products Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: July 8, 2005
Received: July 8, 2005

Dear Mr. Leichter:

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

INDICATIONS FOR USE STATEMENT

510(k) File Number:

Device Name: Merits Health Products Oxygen Concentrator

Indications For Use: The Oxygen Concentrators with the Oxygen Filling accessory are indicated to provide supplemental oxygen to patients in the home and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended for life support nor does it provide any patient monitoring capabilities.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050430