

"510(k) SUMMARY"

MAY 16 2006

9.1 Submitter: Steve Chao
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Prepared – March 25, 2005

9.2 Trade/Proprietary Name: Merits Health Products Oxygen Concentrators
 9.3 Common/Usual Name: Oxygen Concentrator
 9.4 Classification Name: Portable Oxygen Generator

9.5 Comparison to Currently Marketed Devices

The modified 1-liter & 2-liter continuous flow/2.5-6liter for demand flow Merits Health Products Portable Oxygen Concentrators are substantially equivalent to the currently marketed Innosan Travelair "S" Plus Portable Oxygen Concentrator (K971947).

9.6 Device Description

The Merits Health Products Portable Oxygen Concentrator is the prescription device designed to use in an automobile, with power from the automobile's battery and for use with an AC power supply. It is not for life-supporting nor life-sustaining devices. The devices operate through the use of molecular sieve material that binds with the water and nitrogen in filtered room air to leave a gas that is approximately 90% oxygen when delivered to the patient. The compressor creates a vacuum to draw room air into a holding tank. At the same time, downstream of the compressor, the air from the previous cycle is pressurized into one of the two aluminum welded molecular sieve tanks. As the oxygen is forced out of the end of the tank, it enters a "T" fitting that directs most of the gas to flush the nitrogen out of the second molecular sieve tank into the ambient air. The remaining oxygen is delivered to the patient. On the next cycle, the air is directed into the second molecular sieve tank with the oxygen generated flushing the first tank and continuing the supply to the patient. This repetitive cycle generates the oxygen necessary to flush and prepare the saturated sieve tank while supplying the patient with a continuous flow of high concentration oxygen.

This submission covers a model that has 1-liter & 2-liters per minute continuous flow output and 2-6 liters per minute for demand flow which is actuated by breathing and detecting oxygen concentration whenever greater than 85%. An oxygen alarm is built in the oxygen concentrator.

9.7 Indications for Use

The Portable Oxygen Concentrators are intended to provide supplemental oxygen when the patient is away from their primary home oxygen source. The devices are not intended for life support nor do they provide any patient monitoring capabilities.

9.8 Technological Characteristics

The oxygen concentrator operates by using molecular sieve material to absorb water and nitrogen from filtered air. The resulting gas has an increased concentration of oxygen. Demand flow delivery systems have been in use on portable oxygen sources for many years. These technologies are well established and have been used in other legally marketed products. There are no major technologies differences.

9.9 Performance Data

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

9.10 Conclusion

Based on the design, performance specifications and testing and intended use, the Merits Health Products Oxygen Concentrators are substantially equivalent to the currently marketed device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2006

Mr. Steve Chao
Merits Health Products Company, Limited
9, Road 36,
Taichung Industrial Park
Taichung, Taiwan R.O.C.

Re: K053230
Trade/Device Name: Merits Health Products Oxygen Concentrator
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: March 16, 2006
Received: March 21, 2006

Dear Mr. Chao:

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.

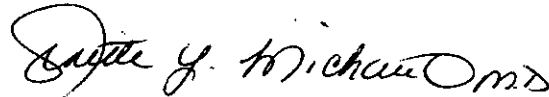
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

510(k) File Number: K053230

Device Name: Merits Health Products Oxygen Concentrator

Indications For Use: The Oxygen Concentrators are indicated for provide supplemental oxygen when the patient is away from their primary home oxygen source. The devices are not intended for life support nor do they provide any patient monitoring capabilities.

Prescription Use V
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 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)



Merits Health Products, General Hospital,
Con Control, Lental Devices

Number: ~~K053230~~ K053230