MAR 2 3 2006

K053229

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY"

9.1 Submitter:

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Prepared – March 1, 2005

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

9.5 Comparison to Currently Marketed Devices

The modified 10-liter Merits Health Products Oxygen Concentrators are substantially equivalent to the currently marketed 5-liter Merits Health Products Oxygen Concentrators (K011844) in main structure. And the functions are substantially equivalent to the 10-liter INTEGRA OXYGEN CONCENTRATOR, MODEL 6323A-OM-10 (K042262). The oxygen driven nebulizer option are substantially equivalent to the currently marketed 5-liter AIRSEP NEWLIFE AIR OUTLET OPTION (K944020) which incorporates a nebulizer with concentrator. The equivalence is supported by the attached documentation.

9.6 Device Description

The Merits Health Products Oxygen Concentrators are prescription devices designed to provide an inexpensive supply of supplemental oxygen in a home or institution without a continuous source of purified oxygen. They are 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 93% 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 first chamber of the dual-chambers aluminum extruded molecular sieve tank. As the oxygen is forced out of the end of the first chamber and then enters the Oxygen tank for patient use. As the remaining Oxygen flush the nitrogen out of the first molecular sieve chamber into the ambient air, the air is directed into the second molecular sieve chamber 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.

Optional oxygen-driven-nebulizer is provided for patients who are prscribed for oxygen aerosol therapy by physician, using higher purity oxygen to drive a nebulizer while oxygen therapy is being undertaken. Optional oxygen-driven-nebulizer allows a single unit to meet the different needs of oxygen or oxygen-aerosol therapy patients.

This submission covers a model that will have a maximum output of 10-liters per minute as compared to the currently marketed model. Options will include an Oxygen alarm, pediatric flowmeter and nebulizer.

9.7 Intend Use

The Oxygen Concentrators are intended for the administration of supplemental oxygen up to 10 LPM. Our proposed Oxygen-Driven Nebulizer option is intended to provide higher purity of oxygen to drive the nebulizer, pursuant to prescribed oxygen-aersol therapy application by physician. The device is not intended for life support nor does it 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 oxygen purity, This technology is well established and has been used in other legally marketed products. There are no major technological 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, testing and intended use, the Merits Health Products Oxygen Concentrators are substantially equivalent to the currently marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2006

Mr. Steve Chao
Merits Health Products Company, Limited
9, Road 36
Taichung Industrial Park
Taichung
China (Taiwan) 407

Re: K053229
Trade/Device Name: Merits Health Products Oxygen Concentrator
Regulation Number: 868.5440
Regulation Name: Respiratory gas humidifier
Regulatory Class: II
Product Code: CAW
Dated: February 17, 2006
Received: February 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 (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 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 continue 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/dsma/dsmamain.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: K053229

Device Name: Merits Health Products Oxygen Concentrator

Indications For Use: The Oxygen Concentrators are indicated for the delivery of supplemental oxygen in the home or medical institutions. The devices are not intended for life support nor do they provide any patient monitoring capabilities.

Prescription Use __V__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

[signature]

[illegible] General Hospital
[illegible] Dental Devices

K053229