K091716

APR - 2 2010

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:	Steve Chao Merits Health Products Co., LTD. 9, Road 36, Taichung Industrial Park Taichung, Taiwan R.O.C. Tel: 886-4-2359-4985 ext. 200 Fax: 886-4-2359-4992 E-mail: stevechao@merits.com.tw
9.3	Trade/Proprietary Name:	Merits Health Products Oxygen Filling Accessory
9.4	Common/Usual Name:	Oxygen Concentrator (Accessory)
9.5	Classification Name:	Portable Oxygen Generator 21 CFR 868.5440 73 CAW

9.6 Comparison to Currently Marketed Devices

The modified Merits Health Products Profill Q601 Series Oxygen Filling Accessory is substantially equivalent to the currently marketed Merits Oxygen Filling Accessory (K050430).

9.7 Device Description

The Profill Q601 series 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 flows to the compressor where the oxygen is pressurized and filled into the cylinder. The devices are not sold or labeled as sterile.

SUMMARY OF SAFETY AND EFFECTIVENESS (Con't)

9.8 Indications for Use

The Oxygen Concentrators with the Oxygen Filling accessory are intended 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. They are not intended to sustain or support life.

9.9 Technological Characteristics

The subject and the predicate devices both use the oxygen concentrator as its oxygen source, similar AC-Powered Motors to drive the oxygen compressors. Both the oxygen compressors use cylinders of the same size and material. The oxygen flows in is compressed in the cylinders and then fill into a medical cylinder through the filling connector. The filling time and filling pressure are the same. Both meet the same Safety and EMC requirements. The technological characteristics of the Profill Q601 series oxygen filling machines are the same as the predicate devices.

9.10 Performance Data

The Safety tests under conduct are summarized in the following.

a. Leakage Currents Test
b. Dielectric Strength
c. Rigidity Test
d. Stability Test
e. Heating Test
f. Abnormal operation and fault condition
g. Power cord Test
h. Transformer dielectric strength
i. Ball pressure Test

The regarding electromagnetic compatibility (EMC) tests has been finished are listed in the following.

a. EN60601-1-2
b. EN61000-3-2
c. EN61000-3-3

Verification testing has confirmed the product meets its specifications.

9.11 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 2 2010

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

Re: K091716
Trade/Device Name: The Merits Health Products Profill Q601 Series Oxygen Filling Accessory
Regulation Number: 21CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: March 10, 2010
Received: March 11, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: The Merits Health Products Profill Q601 Series Oxygen Filling Accessory

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091716

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)