K041823

MAY 10 2005

## 9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

**"510(k) SUMMARY"**

| | | |
|---|---|---|
| 9.1 | Trade/Proprietary Name: | Pioneer U121 Series CPAP |
| 9.2 | Common/Usual Name: | CPAP(Continuous Positive Airway Pressure) |
| 9.3 | Classification Name: | Ventilator, Noncontinuous (Respirator) |

9.4 Comparison to Currently Marketed Devices

The Merits Health Products Pioneer U121 Series CPAP are substantially equivalent to the Invacare Polaris CPAP System (K982242).

9.5 Device Description

The Pioneer U121 Series CPAP operates using standard AC Power from a wall outlet. This U121 Series CPAP consists of a motor-driven blower and a microprocessor based control system. The air, which penetrates through the filter, is directed to the motor-driven blower for pressure lift, and then the pressurized air is delivered to the nozzle, located at the front end of this unit.

The pressurized air is delivered to the patient via a flexible tubing, 22 mm internal diameter, and a standard nasal mask with an exhaust port. This device only requires minimal cleaning and periodic dealer service checks to ensure optimum performance.

9.6 Indications for Use

The Pioneer U121 Series CPAP are indicated for treating the adult, suffering from Obstructive Sleep Apnea (OSA), in the home by delivering continuous positive air pressure to the upper airway. The devices are not intended for life support nor do they provide any patient monitoring capabilities.

9.7 Technological Characteristics

This Pioneer U121 Series CPAP consists of a motor-driven blower and a microprocessor based control system. The air, which penetrates through the filter, is directed to the motor-driven blower for pressure lift, and then the pressurized air is delivered to the nozzle, located at the front end of this unit. The microprocessor controls the pressure of air delivered by monitoring the speed of motor-driven blower. This technology is well established and has been used in other legally marketed products. There are no major technological differences.

9.8 Performance Data

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

9.9 Conclusion

Based on the design, performance specifications and testing and intended use, the Merits Health Products Pioneer U121 Series CPAP 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

MAY 10 2005

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

Re: K041823
Trade/Device Name: Pioneer U121 Series CPAP
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 18, 2005
Received: April 21, 2005

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.

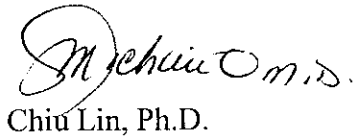
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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

510(k) File Number: K041823

Device Name: Merits Health Products Pioneer U121 Series CPAP

Indications For Use: The Pioneer U121 Series CPAP are indicated for treating the adult, suffering from Obstructive Sleep Apnea (OSA), in the home by delivering continuous positive air pressure to the upper airway. 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K041823